**eTable 1.** **Preexisting conditions, baseline wound parameters and additional baseline parameters relevant for heath economic analyses of the PP population**

|  |  |  |
| --- | --- | --- |
| **Randomized treatment arms** | **NPWT** | **CWT** |
| **Study participants in the PP population,** No. | **157** | **174** |
| **Smoking**, No. (%) | 39 (24.8) | 39 (22.4) |
| Packs / day  Study participants with data available, No.  Mean (SD) | 38  0.9 (0.6) | 38  0.9 (0.5) |
| Years  Study participants with data available, No.  Mean (SD) | 34  33.2 (13.3) | 36  29.5 (14.0) |
| **Alcohol use**, No. (%) | 75 (47.8) | 82 (47.1) |
| Recreational, No. | 65 | 73 |
| Chronic, No. | 10 | 9 |
| **Nutritional status**  Study participants with data available, No. | 157 | 174 |
| Well nourished | 146 | 155 |
| Moderately or suspected of being malnourished | 9 | 16 |
| Severely malnourished | 2 | 3 |
| **Wound surface area at randomization calculated from CRF entries (width and length)** |  |  |
| Study participants with data available, No. | 157 | 174 |
| Mean (SD) | 25.6 (25.5) | 24.8 (27.5) |
| Min-Max | 1.3-200 | 1-170 |
| **Wound volume at randomization calculated from CRF entries (width, length and depth)** |  |  |
| Study participants with data available, No. | 157 | 173 |
| Mean (SD) | 96.8 (125.6) | 89.7 (118.6) |
| Min-Max | 1.3-1000.0 | 0.6-680.0 |
| **Marital status,** No. |  |  |
| Single | 22 | 23 |
| Cohabiting | 19 | 13 |
| Married | 81 | 100 |
| Divorced | 16 | 14 |
| Widowed | 19 | 23 |
| Other | 1 | 1 |
| **Number of children,** Mean (SD) [Min-Max] | 1.5 (1.3) [0-6] | 1.7 (1.3) [0-7] |
| **Location prior to hospitalization,** No. |  |  |
| Home | 137 | 158 |
| Hospital | 18 | 14 |
| Institutional care facility | 0 | 2 |
| Retirement home | 1 | 0 |
| Other | 1 | 1 |

**eTable 2: Employment status and occupational activity at baseline in the PP population**

|  |  |  |
| --- | --- | --- |
| **Randomized treatment arms** | **NPWT** | **CWT** |
| **Study participants in the PP population,** No. | **157** | **174** |
| **Employment status,** No. |  |  |
| Unemployed\* | 9 | 7 |
| Seeking work+ | 2 | 4 |
| Apprenticeship | 0 | 0 |
| Student | 0 | 1 |
| Full-time worker | 49 | 43 |
| Part-time worker | 2 | 14 |
| Casual worker | 0 | 1 |
| Probationary time | 0 | 0 |
| Fixed term worker | 0 | 0 |
| Welfare recipient | 0 | 2 |
| Pensioner | 90 | 103 |
| Other | 6 | 3 |
| **Occupational activity, if participant was working,** No. |  |  |
| Sedentary work | 17 | 17 |
| Light physical work | 12 | 10 |
| Medium physical work | 17 | 23 |
| High physical work | 9 | 9 |

\*+Both “unemployed” and “seeking work” was reported for two study participants. For one study participant both “Employment status: Other = Housewife” and “unemployed” was reported.

**eTable 3: Last and final wound pretreatment procedure (debridement or procedure for thorough wound cleansing) required before initiation of study treatment (documented during randomization visit) in the PP population**

|  |  |  |
| --- | --- | --- |
| **Randomized treatment arms** | **NPWT** | **CWT** |
| **Study participants in the PP population,** No. | **157** | **174** |
| **Location**  Study participants with information available, No.  Bedside  Treatment room  Operation theatre  Other | 137  112  17  7  1 | 153  125  23  4  1 |
| **Anesthesia**  Study participants with information available, No.  Number of study participants with anesthesia performed  Local anesthesia  Regional anesthesia – Peripheral nerve blocks  Regional anesthesia – Epidural and spinal anesthesia  General anesthesia  Number of study participants without anesthesia performed | 137  13  4  1  0  8  124 | 154  6  2  1  0  4  148 |
| **Overall expenditure of time, minutes**  Study participants with information available, No.  Mean (SD)  Min – Max | 129  15.5 (12.7)  1-95 | 146  14.2 (10.9)  2-95 |
| **Performed procedures** (multiple answers possible)  Study participants with information available, No.  Wound cleansing  Wound lavage  Sharp debridement  Surgical debridement  Autolytic debridement  Biological debridement  Enzymatic debridement  Mechanical debridement  Application of wound drainage  Other | 136  115  67  25  7  0  0  1  14  4  27 | 150  128  75  20  5  2  0  2  21  3  32 |
| **Human resources**  **Nursing auxiliary**  Study participants with human resource use, No.  Number of persons involved  Mean (SD) [Min-Max]  Expenditure of time, minutes  Study participants with information available, No.  Mean (SD)  [Min-Max]  **Nursing staff**  Study participants with human resource use, No.  Number of persons involved  Mean (SD) [Min-Max]  Expenditure of time, minutes  Study participants with information available, No.  Mean (SD)  [Min-Max]  **Physician**  Study participants with human resource use, No.  Number of persons involved  Mean (SD) [Min-Max]  Expenditure of time, minutes  Study participants with information available, No.  Mean (SD)  Min-Max  **Study participants with other human resource use,** No. | 11  11  1.1 (0.3) [1-2]  11  21.6 (21.4)  [2-80]  73  72  1.1 (0.3) [1-2]  69  17.1 (16.6)  [2-94]  120  121  1.2 (0.6) [1-4]  118  15.0 (11.6)  [1-72]  5 | 16  18  1.1 (0.2) [1-2]  18  16.2 (23.3)  [2-105]  75  75  1.1 (0.3) [1-2]  72  18.7 (42.9)  [1-360]  126  127  1.1 (0.3) [1-3]  123  17.3 (36.9)  [1-360]  5 |

**eTable 4: Wound treatment performed during Follow Up in the PP population**

|  |  |  |
| --- | --- | --- |
| **Randomized treatment arms** | **NPWT** | **CWT** |
| **Study participants in the PP population,** No. | **157** | **174** |
| **Study participants remaining with an open wound after 42 days,** No. | 53 (33.8%) | 98 (56.3%) |
| **Study participants with follow up treatment information available,** No. | 144 | 160 |
| **Study participants with treatment performed during follow up,** No. | 33 | 64 |
| **Study participants with NPWT during follow up,** No. | 4 | 0 |
| **Length of NPWT during follow up** |  |  |
| Study participants with documented treatment time, No. | 2 | 0 |
| Mean (SD) | 32.0 (48.5) | NA |
| Min - Max | 4 - 88 | NA |
| **Study participants wit CWT during follow up,** No. | 31 | 62 |
| **Length of CWT during follow up** |  |  |
| Study participants with documented treatment time, No. | 20 | 37 |
| Mean (SD) | 36.1 (19.8) | 29.8 (16.6) |
| Min - Max | 5 - 77 | 6 - 86 |

**eTable 5. Surgical wound closure and wound closure by secondary intention within study treatment time of 42 days in the PP population**

|  |  |  |
| --- | --- | --- |
| **Randomized treatment arms** | **NPWT** | **CWT** |
| **Study participants in the PP population,** No. | **157** | **174** |
| *Study participants with wound closure and/or wound closure confirmation visit performed after day 42, No.* | *3 of 157* | *4 of 174* |
| Study participants with wound closure within 42 days but without closure type documented, No. (%) | 0 of 157 (0) | 1 of 174 (0.6) |
| Study participants with **wound closure by secondary intention** and **surgical wound closure** documented (both with date) \*, No. (%) | 3 of 157 (1.9) | 6 of 174 (3.5) |
| Study participants with **wound closure by secondary intention** within 42 days (with date documented), No. (%) | 28 of 157 (17.8) | 28 of 174 (16.1) |
| Study participants with wound closure by secondary intention during inpatient care, No. (%) | 2 of 28 (7.1) | 3 of 28 (10.7) |
| Study participants with wound closure by secondary intention during outpatient care, No. (%) | 26 of 28 (92.9) | 25 of 28 (89.3) |
| Study participants with wound closure by secondary intention with invalid date documented (assignment to in- or outpatient care impossible), No. | 0 | 1 |
| Study participants with **surgical wound closure** (with date documented), No. (%)# | 64 of 157 (41.4) | 31 of 174 (17.8) |
| Study participants with surgical wound closure during inpatient care, No. (%) | 45 of 64 (70.3) | 16 of 31 (51.6) |
| Study participants with surgical wound closure during outpatient care, No. (%)# | 19 of 65 (29.7) | 15 of 31 (48.4) |
| Study participants with surgical wound closure without date documented (assignment to in- or outpatient care impossible) | 1 | 0 |
| Study participants with wound closure procedure performed within 42 days but wound closure was documented during FU#, No. | 1 of 157 | 0 of 174 |
| Study participants with wound closure achieved on day 42 N (%) | 7 (4.5%) | 3 (1.7%) |

\*Because of the documentation of both, surgical wound closures and wound closures by secondary intention, no clear allocation to care sectors is possible for these study participants. #The surgical wound closure procedure was performed during outpatient care.

**eTable 6: Surgical wound closure procedure with location and resource use in the PP population**

|  |  |  |
| --- | --- | --- |
| **Randomized treatment arms** | **NPWT** | **CWT** |
| **Study participants in the PP population,** No. | **157** | **174** |
| **Study participants with surgical wound closure procedure documented,** No. (%) | **72 (45.9 %)** | **38 (21.9 %)** |
| **Location,** No.  Bedside  Treatment Room  Operation Theatre  Other | 14  22  33  1 | 10  15  12  1 |
| **Anesthesia performed,** No.  Yes  Local anesthesia  Regional anesthesia - Peripheral nerve blocks  Regional anesthesia - Epidural and spinal anesthesia  General anesthesia  No | 51  18  1  0  31  29 | 24  13  0  0  11  26 |
| **Time expenditure,** minutes  Mean (SD)  Min-Max | 26 (19)  2-90 | 26 (20)  5-90 |
| **Performed associated procedures,** No. |  |  |
| Wound cleansing | 34 | 27 |
| Wound lavage | 14 | 16 |
| Sharp Debridement | 3 | 1 |
| Surgical Debridement (in the operating theatre) | 10 | 17 |
| Autolytic Debridement | 1 | 0 |
| Biological Debridement (larval (maggot) therapy) | 0 | 0 |
| Enzymatic Debridement | 0 | 0 |
| Mechanical Debridement | 2 | 0 |
| Application of wound drainage | 20 | 6 |
| Secondary Suture | 57 | 31 |
| Skin Graft | 0 | 0 |
| Flap | 0 | 0 |
| Other | 11 | 5 |
| Dressing application | 1 | 3 |
| Electric hemostasis | 0 | 1 |
| NPWT removal | 1 | 0 |
| NPWT removal and application of dressing | 1 | 0 |
| Sterile strips application | 0 | 1 |
| Suture / staples removal | 8 | 0 |
| **Human resources use** |  |  |
| **Nursing auxiliary** |  |  |
| **Number of procedures with nursing auxiliary use** | **9** | **6** |
| **Personnel expenditure,** No. | **9** | **6** |
| Mean (SD) | 1 (0) | 1 (0) |
| Min-Max | 1-1 | 1-1 |
| **Time expenditure,** minutes |  |  |
| Study participants with information available, No. | 9 | 6 |
| Mean (SD) | 55 (32) | 45 (38) |
| Min-Max | 10-100 | 5-92 |
| **Nursing staff** |  |  |
| **Number of procedures with nursing auxiliary use** | 54 | 23 |
| **Personnel expenditure,** No. | 73 | 31 |
| Mean (SD) | 1 (1) | 1 (1) |
| Min-Max | 1-2 | 1-2 |
| **Time expenditure,** minutes |  |  |
| Study participants with information available No. | 54 | 24 |
| Mean (SD) | 31 (30) | 31 (27) |
| Min-Max | 2-145 | 5-92 |
| **Physician** |  |  |
| **Number of procedures with nursing auxiliary use** | 66 | 34 |
| **Personnel expenditure,** No. | 101 | 71 |
| Mean (SD) | 1 (1) | 1 (0) |
| Min-Max | 1-3 | 1-2 |
| **Time expenditure,** minutes |  |  |
| Study participants with information available No. | 65 | 35 |
| Mean (SD) | 28 (27) | 27 (32) |
| Min-Max | 2-140 | 5-180 |
| **Number of procedures with other human resources**  Anesthesiologist  Anesthesiologist in Stand-by  Intern  Medical student in practical year  Resident physician  Senior physician | 12  7  1  1  1  1  1 | 5  2  0  3  0  0  0 |

**eTable 7: Wound closure documentation in the PP population**

|  |  |  |
| --- | --- | --- |
| **Randomized treatment arms** | **NPWT** | **CWT** |
| **Study participants in the PP population,** No. | **157** | **174** |
| Study participants with complete, sustained and verified wound closure (= wound closures conform to the criteria in the study protocol) during the study treatment time of 42 days\*, No. (%) | 75 (47.8%) | 48 (27.6%) |
| Study participants with closed wound which violated at least one of the criteria for complete, sustained, and verified wound closure, No. (%) | 22 (14.0%) | 20 (11.5%) |
| **∑ Number of study participants with closed wound documented within 42 days** | **97 (61.8%)** | **68 (39.1%)** |
| Study participants with wound closure documented during follow up with a date, No. | 35 | 64 |
| Study participants with wound closure documented during follow up without a date+#, No. | 4 | 12 |
| Study participants with wound closure during follow up at a date later than 135 days (with date set to 135 days), No. | 1 | 0 |
| Study participants with wound closure visit and/or wound closure confirmation visit performed during follow up, No. | 3 | 4 |
| **∑ Number of study participants with closed wound documented during follow up after day 42** | **43 (27.4%)** | **80 (46.0%)** |

\* Significant difference between the treatment arms (p<.001) (Results were reported: doi:10.1001/jamasurg.2020.0414)

+For one study participant, wound closure was documented during the follow up visit after 87 days (August 18, 2015) but without giving a concrete date only indicating July. During the study visit at end of maximum treatment time after 42 days, the wound was documented to be still open. For this study participant wound closure was assumed at July 15, 2015.

#For study participants with wound closure documented during follow up but without indicating a date, the median of all wound closures that occurred during the follow up period (day 71) was assumed and used for further analyses.

**eTable 8: Human resources required for dressing changes in the PP population**

|  |  |  |  |
| --- | --- | --- | --- |
| **Randomized treatment arms / Statistical significance** | **NPWT** | **CWT** | **P-value\*** |
| **Study participants in the PP population,** No. | **157** | **174** | **NA** |
| **Physician contacts for dressing changes** |  |  |  |
| Study participants with data available, No. | 124 | 125 | .011 |
| Mean (SD) | 5.6 (4.3) | 8.3 (7.9) |
| Min - Max | 1 - 25 | 1 - 42 |
| **Physician`s time per study participant, minutes** |  |  |  |
| Study participants with data available, No. | 124 | 125 | .585 |
| Mean (SD) | 116.6 (99.9) | 113.2 (103.4) |
| Min - Max | 5.0 - 536.0 | 1.0 – 503.0 |
| **Nurse contacts for dressing changes** |  |  |  |
| Study participants with data available, No. | 113 | 128 | <.001 |
| Mean (SD) | 7.9 (9.5) | 15.6 (11.8) |
| Min - Max | 1 - 79 | 1 - 72 |
| **Nurse`s time per study participant, minutes** |  |  |  |
| Study participants with data available, No. | 112 | 128 | .001 |
| Mean (SD) | 154.0 (212.0) | 223.1 (183.8) |
| Min - Max | 5.0 – 2086.0 | 5.0 - 1061.0 |
| **Nursing assistance contacts for dressing changes** |  |  |  |
| Study participants with data available, No. | 21 | 15 | .568 |
| Mean (SD) | 2.3 (1.6) | 2.7 (1.9) |
| Min - Max | 1 - 6 | 1 - 8 |
| **Nursing assistance`s time per study participant, minutes** |  |  |  |
| Study participants with data available, No. | 20 | 15 | .030 |
| Mean (SD) | 64.0 (45.7) | 34.4 (24.8) |
| Min - Max | 12.0 - 180.0 | 5.0 - 90.0 |
| **Relatives contacts for dressing changes** |  |  |  |
| Study participants with data available, No. | 13 | 35 | .514 |
| Mean (SD) | 9.0 (9.3) | 10.3 (9.4) |
| Min - Max | 1 - 26 | 1 - 36 |
| **Relative`s time per study participant, minutes** |  |  |  |
| Study participants with data available, No. | 12 | 34 | .514 |
| Mean (SD) | 128.6 (155.8) | 116.2 (148.3) |
| Min - Max | 5.0 – 500.0 | 5.0 – 840.0 |

\*Mann-Whitney U test

**eTable 9:** **Time and human resources required for inpatient and outpatient dressing changes during NPWT, post NPWT CWT period and CWT in the PP population**

|  |  |  |  |
| --- | --- | --- | --- |
| **Randomized treatment arms** | **NPWT in the NPWT-arm** | **Post NPWT CWT period in the NPWT arm** | **CWT in the CWT arm** |
| **Study participants in the PP population,** No. | **157** | **157** | **174** |
| **Study participants with inpatient treatment, No.** | **144** | **30** | **158** |
| **Number of inpatient dressing changes per study participant** |  |  |  |
| Study participants with data available, No.  Mean (SD) | 118  4.1 (3.2) | 24  7.1 (8.3) | 130  10.6 (10.3) |
| Min - Max | 1 - 20 | 1 - 42 | 1 - 71 |
| **Time required for inpatient dressing changes per study participant, minutes** |  |  |  |
| Study participants with data available, No. | 117 | 23 | 130 |
| Mean (SD) | 96.2 (113.1) | 74.0 (64.1) | 128.9 (128.4) |
| Min - Max | 10 – 951 | 5 – 274 | 5 - 765 |
| **Time required per inpatient dressing change, minutes** |  |  |  |
| Number of dressing changes with time recording | 476 | 166 | 1340 |
| Mean (SD) | 23.6 (17.7) | 10.3 (9.1) | 12.5 (6.7) |
| Min - Max | 1 - 150 | 1 – 95 | 1 – 65 |
| **Physician contacts for inpatient dressing changes** |  |  |  |
| Study participants with data available, No. | 104 | 15 | 101 |
| Mean (SD) | 3.5 (2.5) | 4.4 (3.8) | 6.0 (7.2) |
| Min - Max | 1 - 16 | 1 – 12 | 1 – 42 |
| **Time expenditure per dressing change, minutes** |  |  |  |
| Study participants with data available, No. | 103 | 15 | 101 |
| Mean (SD) | 24.2 (17.7) | 14.2 (12.0) | 12.9 (7.8) |
| Min – Max | 1 – 150 | 1 – 95 | 1 – 50 |
| **Nurse contacts for inpatient dressing changes** |  |  |  |
| Study participants with data available, No. | 90 | 19 | 105 |
| Mean (SD) | 3.0 (2.3) | 6.5 (8.6) | 8.3 (9.3) |
| Min - Max | 1 - 16 | 1 – 40 | 1 – 71 |
| **Time expenditure per dressing change, minutes** |  |  |  |
| Study participants with data available, No. | 90 | 18 | 105 |
| Mean (SD) | 24.7 (19.1) | 9.9 (10.2) | 12.6 (6.1) |
| Min - Max | 1 - 150 | 1 – 95 | 2 – 65 |
| **Nursing assistance contacts for inpatient dressing changes** |  |  |  |
| Study participants with data available, No. | 14 | 3 | 14 |
| Mean (SD) | 2.1 (1.6) | 1.3 (0.6) | 2.3 (1.3) |
| Min - Max | 1 - 6 | 1 – 2 | 1 – 5 |
| **Time expenditure per dressing change, minutes** |  |  |  |
| Study participants with data available, No. | 14 | 3 | 14 |
| Mean (SD) | 30.0 – 19.6 | 43.8 (35.2) | 11.4 (4.0) |
| Min - Max | 6 - 110 | 15 – 95 | 3 – 20 |
| **Relatives contacts for inpatient dressing changes** |  |  |  |
| Study participants with data available, No. | 1 | 0 | 4 |
| Mean (SD) | 1 (NA) | NA | 8.5 (13.7) |
| Min - Max | 1 - 1 | NA | 1 – 29 |
| **Time expenditure per dressing change, minutes** |  |  |  |
| Study participants with data available, No. | 1 | 0 | 4 |
| Mean (SD) | 100.0 (NA) | NA | 10.4 (3.6) |
| Min - Max | 100 - 100 | NA | 5 – 30 |
| **Number of study participants with outpatient treatment** | **68** | **57** | **141** |
| **Number of outpatient dressing changes per study participant** |  |  |  |
| Study participants with data available, No.  Mean (SD) | 57  5.2 (5.4) | 50  9.5 (9.7) | 118  15.0 (11.3) |
| Min - Max | 1 - 36 | 1 - 42 | 1 - 47 |
| **Time required per outpatient dressing change** |  |  |  |
| Number of dressing changes with time recording | 288 | 440 | 1708 |
| Mean (SD) | 22.9 (14.7) | 14.8 (10.6) | 14.9 (8.4) |
| Min - Max | 2 - 97 | 1 - 100 | 1 - 90 |
| **Time required for outpatient dressing changes per study participant** |  |  |  |
| Study participants with data available, No. | 57 | 49 | 118 |
| Mean (SD) | 115.5 (127.9) | 132.7 (200.3) | 215.6 (186.0) |
| Min - Max | 10 – 751 | 5 – 1302 | 3 – 888 |
| **Physician contacts for outpatient dressing changes** |  |  |  |
| Study participants with data available, No. | 45 | 33 | 83 |
| Mean (SD) | 3.8 (3.3) | 2.6 (1.6) | 5.3 (6.1) |
| Min - Max | 1 – 16 | 1 – 6 | 1 – 39 |
| **Time expenditure per dressing change, minutes** |  |  |  |
| Study participants with data available, No. | 45 | 32 | 82 |
| Mean (SD) | 21.7 (14.3) | 15.7 (12.4) | 15.0 (10.4) |
| Min - Max | 2 - 90 | 1 - 70 | 1 - 60 |
| **Nurse contacts for outpatient dressing change** |  |  |  |
| Study participants with data available, No. | 42 | 41 | 95 |
| Mean (SD) | 4.6 (5.6) | 7.4 (8.1) | 11.9 (9.2) |
| Min - Max | 1 - 36 | 1 - 41 | 1 - 38 |
| **Time expenditure per dressing change, minutes** |  |  |  |
| Study participants with data available, No. | 42 | 39 | 95 |
| Mean (SD) | 24.5 (15.4) | 16.3 (12.0) | 16.8 (8.6) |
| Min - Max | 3 - 97 | 1 - 100 | 1 - 90 |
| **Nursing assistance contacts for dressing change** |  |  |  |
| Study participants with data available, No. | 4 | 3 | 3 |
| Mean (SD) | 1.8 (1.0) | 2.7 (2.9) | 2.7 (1.2) |
| Min - Max | 1 - 3 | 1 - 6 | 2 - 4 |
| **Time expenditure per dressing change, minutes** |  |  |  |
| Study participants with data available, No. | 4 | 2 | 3 |
| Mean (SD) | 32.1 (22.7) | 20.0 (14.1) | 18.8 (11.9) |
| Min - Max | 15 - 80 | 10 - 30 | 10 - 40 |
| **Relatives contacts for outpatient dressing change** |  |  |  |
| Study participants with data available, No. | 2 | 10 | 34 |
| Mean (SD) | 6.5 (6.4) | 10.3 (10.0) | 9.6 (8.9) |
| Min - Max | 2 - 11 | 1 - 26 | 1 - 36 |
| **Time expenditure per dressing change, minutes** |  |  |  |
| Study participants with data available, No. | 13 | 89 | 314 |
| Mean (SD) | 28.9 (3.0) | 12.0 (5.5) | 11.5 (6.7) |
| Min - Max | 20 - 30 | 5 - 20 | 1 - 60 |

**eTable 10: Dressing material and wound dressing use during in- and outpatient care in the PP population**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Randomized treatment arms** | **During inpatient care in the NPWT arm** | **During inpatient care in the CWT arm** | **During outpatient care in the NPWT arm** | **During outpatient care in the CWT arm** |
| **Study participants in the PP population,** No. | **157** | **174** | **157** | **174** |
| **Number of study participants with dressing material use (which was used for fixation, cushioning and absorption of liquid, but was not directly placed on the wound)** | **100 of 157** | **114 of 174** | **77** **of 80** | **110** **of 112** |
| Sterile compresses | 97 | 110 | 73 | 105 |
| Stretch bandages | 33 | 70 | 28 | 66 |
| Fixation material / patches / plasters / strips | 18 | 26 | 39 | 54 |
| Absorbent dressings | 11 | 38 | 15 | 33 |
| Unsterile compresses | 11 | 16 | 7 | 15 |
| Swabs | 7 | 8 | 8 | 17 |
| Unsterile film | 6 | 12 | 9 | 10 |
| Sterile film | 8 | 7 | 6 | 4 |
| Bandage gauze | 2 | 7 | 6 | 5 |
| Self-adhesive non-woven (fleece) dressings | 0 | 3 | 2 | 3 |
| Abdominal bandages | 1 | 4 | 0 | 2 |
| Pads / mats / plates | 1 | 4 | 0 | 2 |
| Sets / kits | 1 | 2 | 0 | 2 |
| Superabsorber | 0 | 2 | 1 | 2 |
| Antimicrobial dressings | 0 | 1 | 1 | 2 |
| Abdominal cloths | 0 | 0 | 0 | 2 |
| Other material without or unidentifiable description | 5 | 9 | 7 | 9 |
| **Number of study participants with wound dressing use documented** | **47** **of 157** | **83** **of 174** | **44** **of 80** | **94** **of 112** |
| Antimicrobial dressings | 8 | 37 | 11 | 33 |
| Alginate without silver | 7 | 23 | 8 | 19 |
| Soft-adhesive Foam bandage without silver | 6 | 16 | 14 | 15 |
| Self-adhesive foam bandages without silver | 3 | 13 | 3 | 21 |
| Hydrofiber with silver | 1 | 19 | 2 | 17 |
| Hydrofiber without silver | 1 | 11 | 1 | 22 |
| Self-adhesive non-woven (fleece) dressings | 4 | 10 | 7 | 13 |
| Hydrocolloid without silver | 7 | 4 | 14 | 5 |
| Transparent film | 5 | 8 | 4 | 8 |
| Alginate with silver | 2 | 13 | 1 | 7 |
| Superabsorber | 0 | 11 | 1 | 7 |
| Composites without silver | 1 | 8 | 2 | 7 |
| Non-adhesive foam dressings | 2 | 4 | 2 | 6 |
| Absorbent dressings | 1 | 4 | 1 | 7 |
| Plaster / patches / strips | 6 | 5 | 1 | 1 |
| Abdominal cloth | 8 | 2 | 0 | 0 |
| Mesh | 4 | 3 | 0 | 1 |
| Gauze without silver | 0 | 3 | 0 | 3 |
| Composites with silver | 1 | 4 | 0 | 1 |
| Silicone dressings | 1 | 0 | 2 | 2 |
| Soft-adhesive foam bandage with silver | 0 | 2 | 0 | 2 |
| Self-adhesive foam bandages with silver | 0 | 1 | 1 | 1 |
| Active coal compresses | 0 | 1 | 0 | 1 |
| Hydrogel | 0 | 0 | 1 | 1 |
| Hydrocolloid with silver | 0 | 1 | 0 | 0 |
| Non-woven non-adhesive dressings / fleece compresses | 0 | 1 | 0 | 0 |
| Medical honey | 0 | 0 | 1 | 0 |
| Other material without or unidentifiable description | 4 | 6 | 7 | 7 |

**eTable 11: Human resources for wound-related procedures performed within 42 days in the PP population**

|  |  |  |  |
| --- | --- | --- | --- |
| **Randomized treatment arms / Statistical significance** | **NPWT** | **CWT** | **P-value\*** |
| **Study participants in the PP population,** No. | **157** | **174** | NA |
| **Number of wound-related procedures involving nursing auxiliary** | 117 | 407 | NA |
| **Total time expenditure for nursing auxiliary, minutes per study participant** |  |  |  |
| Mean (SD) | 10 (38) | 22 (108) | .482 |
| Min - Max | 0 – 280 | 0 – 1263 |
| **Number of wound-related procedures involving nurses** | 1992 | 3863 | NA |
| **Total time expenditure for nursing staff, minutes per study participant** |  |  |  |
| Mean (SD) | 108 (176) | 157 (229) | .038 |
| Min - Max | 0 – 1060 | 0 – 1466 |
| **Number of wound-related procedures involving assistant physicians** | 1076 | 1600 | NA |
| **Total time expenditure for assistant physician (resident)**, **minutes per study participant** |  |  |  |
| Mean (SD) | 64 (105) | 69 (128) | .155 |
| Min - Max | 0 – 920 | 0 – 1055 |
| **Number of wound-related procedures involving specialist physicians** | 671 | 823 | NA |
| **Total time expenditure for specialist physician (consultant)**, **minutes per study participant** |  |  |  |
| Mean (SD) | 48 (92) | 34 (68) | .061 |
| Min - Max | 0 – 580 | 0 – 500 |

\*Mann-Whitney U test; NA= not applicable

**eTable 12: Wound-related procedures performed during inpatient and outpatient care in the PP population**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Randomized treatment arms** | **Inpatient NPWT** | **Inpatient CWT** | **Outpatient NPWT** | **Outpatient CWT** |
| **Study participants in the PP population,** No. | **157** | **174** | **157** | **174** |
| **Study participants with wound cleansing,** No. | **113** | **137** | **100** | **141** |
| **Wound cleansings per study participant** |  |  |  |  |
| Mean (SD) | 5.2 (6.5) | 9.1 (9.8) | 8.4 (8.4) | 12.5 (11.4) |
| Min – Max | 1 - 48 | 1 - 48 | 1 - 56 | 1 - 73 |
| **Time expenditure per study participant, minutes** |  |  |  |  |
| Mean (SD)  Min – Max | 7.0 (7.3)  1 - 70 | 6.3 (5.1)  1 - 45 | 6.3 (6.1)  1 – 39 | 6.3 (5.6)  1 – 60 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary | 29 (9.7) | 69 (6.6) | 32 (7.0) | 191 (11.4) |
| Nursing staff | 353 (7.6) | 837 (6.5) | 540 (7.4) | 972 (7.6) |
| Assistant physician (resident) | 274 (8.6) | 467 (7.0) | 181 (6.5) | 317 (7.5) |
| Specialist physician (consultant) | 143 (5.8) | 182 (8.1) | 117 (7.3) | 228 (6.5) |
| **Study participants with wound lavage,** No. | **71** | **73** | **44** | **73** |
| **Wound lavages per study participant** |  |  |  |  |
| Mean (SD) | 4.2 (4.2) | 8.0 (8.6) | 6.6 (6.6) | 9.4 (9.2) |
| Min – Max | 1-26 | 1-42 | 1-31 | 1-35 |
| **Time expenditure per study participant, minutes** |  |  |  |  |
| Mean (SD)  Min – Max | 7.7 (8.8)  1 – 70 | 6.2 (5.5)  1 – 43 | 6.3 (6.4)  1 – 45 | 6.9 (7.8)  1 – 90 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary | 10 (35.5) | 36 (6.4) | 5 (4.6) | 51 (9.2) |
| Nursing staff | 147 (8.8) | 318 (5.9) | 146 (7.4) | 280 (8.3) |
| Assistant physician (resident) | 191 (7.5) | 272 (6.0) | 59 (5.8) | 182 (6.7) |
| Specialist physician (consultant) | 75 (11.5) | 55 (8.6) | 28 (6.3) | 48 (5.8) |
| **Study participants with sharp debridement (using scalpel or curette at bedside),** No. | **18** | **16** | **18** | **16** |
| **Sharp debridements per study participant** |  |  |  |  |
| Mean (SD) | 2.0 (1.9) | 4.1 (5.0) | 1.7 (1.0) | 2.4 (2.2) |
| Min – Max | 1 - 8 | 1 - 21 | 1 - 4 | 1 - 7 |
| **Time expenditure per study participant,** minutes |  |  |  |  |
| Mean (SD)  Min – Max | 8.8 (10.0)  1 – 60 | 7.7 (4.9)  2 – 25 | 11.5 (13.3)  1 – 50 | 6.6 (4.4)  2 – 20 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary | 1 (25.0) | 9 (5.7) | 1 (20.0) | 1 (4.0) |
| Nursing staff | 12 (6.7) | 11 (7.8) | 9 (7.7) | 11 (5.2) |
| Assistant physician (resident) | 27 (10.1) | 51 (8.3) | 15 (18.9) | 25 (7.8) |
| Specialist physician (consultant) | 7 (8.0) | 10 (11.7) | 9 (5.6) | 4 (7.5) |
| **Number of study participants with surgical debridement (in the operation theatre)** | **23** | **10** | **2** | **4** |
| **Surgical debridements per study participant** |  |  |  |  |
| Mean (SD) | 2.4 (2.4) | 1.1 (0.3) | 1.5 (0.7) | 1.3 (0.5) |
| Min – Max | 1 - 10 | 1 - 2 | 1 - 2 | 1 - 2 |
| **Time expenditure per study participant, minutes** |  |  |  |  |
| Mean (SD)  Min – Max | 14.5 (14.6)  2 – 69 | 26.3 (23.7)  3 - 75 | 11.0 (3.6)  8 – 15 | 7.3 (5.7)  2 – 15 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary | 2(8.0) | 1(75.0) | 0 (0) | 0 (0) |
| Nursing staff | 47(13.0) | 8 (19.1) | 3 (11.0) | 1 (8.0) |
| Assistant physician (resident) | 34 (12.5) | 8 (22.9) | 1 (15.0) | 1 (4.0) |
| Specialist physician (consultant) | 39 (13.9) | 8 (22.0) | 2 (9.0) | 4 (10.0) |
| **Number of study participants with autolytic debridement (facilitation of the body`s own mechanisms of debridement with appropriate dressings)** | **2** | **6** | **0** | **8** |
| **Autolytic debridements per study participant** |  |  |  |  |
| Mean (SD) | 1.0 (0) | 8.0 (4.6) | NA | 4.5 (2.7) |
| Min – Max | 1 - 1 | 3 - 14 |  | 1 - 9 |
| **Time expenditure per study participant, minutes** |  |  |  |  |
| Mean (SD)  Min – Max | 30 (0)  30 – 30 | 2.3 (2.7)  1 – 14 | NA | 2.2 (2.2)  1 – 10 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary | 1 (30.0) | 0 (0) | NA | 0 (0) |
| Nursing staff | 1 (30.0) | 48 (3.8) |  | 36 (1.9) |
| Assistant physician (resident) | 1 (30.0) | 0 (0) |  | 0 (0) |
| Specialist physician (consultant) | 1 (30.0) | 0 (0) |  | 0 (0) |
| **Number of study participants with biological debridement (larval (maggot) therapy)** | **0** | **0** | **0** | **1** |
| **Biological debridements per study participant** |  |  |  |  |
| Mean (SD) | NA | NA | NA | 1 (0) |
| Min – Max |  |  |  | 1 – 1 |
| **Time expenditure per study participant,** minutes |  |  |  |  |
| Mean (SD)  Min – Max | NA | NA | NA | 10 (0)  10 - 10 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary | NA | NA | NA | 0 (0) |
| Nursing staff |  |  |  | 0 (0) |
| Assistant physician (resident) |  |  |  | 1 (10.0) |
| Specialist physician (consultant) |  |  |  | 0 (0) |
| **Number of study participants with enzymatic debridement** | **0** | **3** | **2** | **2** |
| **Enzymatic debridements per study participant** |  |  |  |  |
| Mean (SD) | NA | 3.1 (3.1) | 3.0 (2.0) | 2.5 (1.5) |
| Min – Max |  | 1 – 10 | 1 – 5 | 1 - 4 |
| **Time expenditure per study participant, minutes** |  |  |  |  |
| Mean (SD)  Min – Max | NA | 24.1 (23.3)  7 – 78 | 6.3 (2.9)  3 – 8 | 5.0 (3.4)  3 – 10 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary N | NA | 0 (0) | 0 (0) | 0 (0) |
| Nursing staff N |  | 30 (29.2) | 6 (7.2) | 0 (0) |
| Assistant physician (resident) N |  | 7 (57.4) | 0 (0) | 4 (5.0) |
| Specialist physician (consultant) N |  | 0 (0) | 0 (0) | 0 (0) |
| **Number of study participants with mechanical debridement (wet-to-dry dressings)** | **11** | **23** | **13** | **27** |
| **Mechanical debridements per study participant** |  |  |  |  |
| Mean (SD) | 6.3 (6.1) | 11.5 (15.6) | 6.5 (7.4) | 9.0 (8.3) |
| Min – Max | 1 - 23 | 1 - 70 | 1 - 22 | 1 - 35 |
| **Time expenditure per study participant, minutes** |  |  |  |  |
| Mean (SD)  Min – Max | 13.6 (10.5)  3 – 30 | 7.1 (3.8)  2 – 30 | 13.8 (10.3)  2 – 30 | 7.9 (5.1)  1 – 30 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary | 4 (13.0) | 3 (7.3) | 6 (30.0) | 0 (0) |
| Nursing staff | 59 (13.6) | 203 (7.1) | 75 (13.5) | 160 (10.0) |
| Assistant physician (resident) | 9 (9.1) | 67 (7.8) | 8 (8.5) | 34 (6.8) |
| Specialist physician (consultant) | 28 (19.0) | 40 (7.1) | 10 (14.0) | 52 (11.0) |
| **Number of study participants with application of wound drainage** | **20** | **9** | **3** | **1** |
| **Drainage applications per study participant** |  |  |  |  |
| Mean (SD) | 1.7 (2.1) | 3.9 (5.7) | 1.7 (0.6) | 26 (-) |
| Min – Max | 1 - 10 | 1 - 18 | 1 - 2 | 26 - 26 |
| **Time expenditure per study participant, minutes** |  |  |  |  |
| Mean (SD)  Min – Max | 6.4 (7.4)  1 – 37 | 10.1 (9.2)  1 – 31 | 12.0 (3.6)  8 – 15 | 13.6 (2.2)  10-15 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary | 1 (5.0) | 0 (0) | 1 (15.0) | 0 (0) |
| Nursing staff | 29 (7.1) | 35 (6.0) | 3 (8.7) | 26 (13.1) |
| Assistant physician (resident) | 20 (6.8) | 5 (12.0) | 1 (15.0) | 0 (0) |
| Specialist physician (consultant) | 22 (5.4) | 4 (10.3) | 2 (15.0) | 0 |
| **Number of study participants with other procedures performed** | **96** | **71** | **65** | **70** |
| **Other procedures per study participant** |  |  |  |  |
| Mean (SD) | 4.5 (8.6) | 7.5 (10.0) | 6.1 (6.5) | 9.1 (11.1) |
| Min – Max | 1 - 76 | 1 - 43 | 1 - 32 | 1 - 52 |
| **Time expenditure per study participant, minutes** |  |  |  |  |
| Mean (SD)  Min – Max | 12.3 (12.1)  1 – 105 | 6.6 (7.5)  1 – 60 | 9.1 (6.5)  1 – 37 | 6.3 (5.9)  1 – 45 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary | 8 (40.6) | 22 (6.4) | 16 (9.1) | 23 (5.0) |
| Nursing staff | 286 (9.6) | 464 (5.8) | 241 (8.8) | 355 (5.9) |
| Assistant physician (resident) | 178 (15.0) | 67 (8.5) | 67 (10.8) | 65 (11.3) |
| Specialist physician (consultant) | 122 (16.0) | 67 (7.1) | 62 (11.6) | 104 (5.3) |

**eTable 13: Wound-related procedures performed during the post-NPWT CWT period in the PP population**

|  |  |  |  |
| --- | --- | --- | --- |
| **Randomized treatment arms / Statistical significance** | **NPWT** | **CWT** | **P-value\*** |
| **Study participants in the PP population,** No. | **157** | **174** | **NA** |
| **Study participants with inpatient post NPWT CWT period procedures,** No. | 29 | NA | NA |
| **Inpatient post NPWT CWT period wound related procedures per study participant** |  |  |  |
| Mean (SD) | 14.3 (21.1) | NA | NA |
| Min – Max | 2 – 114 |
| **Time expenditure per study participant, minutes,** No. | 29 | NA | NA |
| Mean (SD) | 100 (172) | NA | NA |
| Min – Max | 4 – 890 |
| **Study participants with outpatient post NPWT CWT period procedures,** No. | 53 | NA | NA |
| **Outpatient post NPWT CWT period wound related procedures per study participant,** No. |  |  |  |
| Mean (SD) | 14.0 (11.2) | NA | NA |
| Min – Max | 1 – 47 |
| **Time expenditure per study participant, minutes,** No. | 52 | NA | NA |
| Mean (SD) | 105 (133) | NA | NA |
| Min – Max | 2 – 691 |

**eTable 14: Wound-related procedures performed during the inpatient and outpatient post-NPWT CWT period in the PP population (NPWT arm only)**

|  |  |  |
| --- | --- | --- |
| **Treatment sector** | **Inpatient** | **Outpatient** |
| **Study participants with wound-related procedures during the post-NPWT CWT period in the PP population,** No. | 29 | 53 |
| **Study participants with wound cleansing,** No. | 23 | 47 |
| **Wound cleansings per study participant** |  |  |
| Mean (SD) | 7.8 (8.8) | 7.8 (7.5) |
| Min – Max | 1 - 43 | 1 - 36 |
| **Time expenditure per study participant, minutes**  Mean (SD)  Min – Max | 6.2 (8.4)  1 – 70 | 5.8 (4.9)  1 – 39 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |
| Nursing auxiliary | 14 (8.4) | 3 (6.3) |
| Nursing staff | 116 (8.2) | 264 (7.1) |
| Assistant physician (resident) | 84 (12.5) | 83 (7.0) |
| Specialist physician (consultant) | 18 (8.2) | 27 (4.9) |
| **Number of study participants with wound lavage** | 11 | 23 |
| **Wound lavages per study participant** |  |  |
| Mean (SD) | 6.5 (4.7) | 7.4 (7.8) |
| Min – Max | 1 – 14 | 1 – 30 |
| **Time expenditure per study participant, minutes**  Mean (SD)  Min – Max | 6.7 (6.7)  2 – 35 | 6.0 (5.3)  1 – 20 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |
| Nursing auxiliary | 3 (11.7) | 3 (5.3) |
| Nursing staff | 30 (11.3) | 86 (6.5) |
| Assistant physician (resident) | 52 (9.1) | 25 (7.0) |
| Specialist physician (consultant) | 15 (6.0) | 9 (3.9) |
| **Number of study participants with sharp debridement (using scalpel or curette at bedside)** | 1 | 6 |
| **Sharp debridements per study participant** |  |  |
| Mean (SD) | 2 (NA) | 1.5 (1.2) |
| Min – Max | 2 – 2 | 1 – 4 |
| **Time expenditure per study participant, minutes**  Mean (SD)  Min – Max | 10 (0)  10 – 10 | 12.2 (13.7)  1 – 45 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |
| Nursing auxiliary | 0 (0) | 0 (0) |
| Nursing staff | 2 (10.0) | 3 (16.0) |
| Assistant physician (resident) | 2 (10.0) | 6 (17.0) |
| Specialist physician (consultant) | 0 (0) | 1 (5.0) |
| **Number of study participants with surgical debridement (in the operation theatre)** | 1 | 1 |
| **Surgical debridements per study participant** |  |  |
| Mean (SD) | 1 (-) | 1 (-) |
| Min – Max | 1 – 1 | 1 – 1 |
| **Time expenditure per study participant, minutes**  Mean (SD)  Min – Max | 15 (-)  15 – 15 | 15 (-)  15 – 15 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |
| Nursing auxiliary | 0 (0) | 0 (0) |
| Nursing staff | 1 (15.0) | 1 (15.0) |
| Assistant physician (resident) | 1 (15.0) | 1 (15.0) |
| Specialist physician (consultant) | 0 (0) | 0 (0) |
| **Number of study participants with autolytic debridement (Facilitation of the body`s own mechanisms of debridement with appropriate dressings)** | 1 | 0 |
| **Autolytic debridements per study participant** |  |  |
| Mean (SD) | 1 (-) | NA |
| Min – Max | 1 – 1 |  |
| **Time expenditure per study participant, minutes**  Mean (SD)  Min – Max | 30 (-)  30 – 30 | NA |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  | NA |
| Nursing auxiliary | 1 (30.0) |  |
| Nursing staff | 1 (30.0) |  |
| Assistant physician (resident) | 0 (0) |  |
| Specialist physician (consultant) | 1 (30.0) |  |
| **Number of study participants with biological debridement (larval (maggot) therapy)** | 0 | 0 |
| **Number of study participants with enzymatic debridement** | 0 | 1 |
| **Enzymatic debridements per study participant** |  |  |
| Mean (SD) | NA | 5 (NA) |
| Min – Max |  | 5 – 5 |
| **Time expenditure per study participant, minutes**  Mean (SD)  Min – Max | NA | 8 (0)  8 – 8 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) | NA |  |
| Nursing auxiliary |  | 0 (0) |
| Nursing staff |  | 5 (8.0) |
| Assistant physician (resident) |  | 0 (0) |
| Specialist physician (consultant) |  | 0 (0) |
| **Number of study participants with mechanical debridement (wet-to-dry dressings)** | 3 | 6 |
| **Mechanical debridements per study participant** |  |  |
| Mean (SD) | 11.0 (9.6) | 3.5 (2.6) |
| Min – Max | 4 – 22 | 1 – 8 |
| **Time expenditure per study participant, minutes**  Mean (SD)  Min – Max | 5.0 (2.1)  3 – 10 | 7.8 (6.2)  2 – 20 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |
| Nursing auxiliary | 1 (7.0) | 0 (0) |
| Nursing staff | 31 (5.1) | 21 (8.8) |
| Assistant physician (resident) | 2 (6.0) | 3 (6.0) |
| Specialist physician (consultant) | 4 (3.0) | 0 (0) |
| **Number of study participants with application of wound drainage** | 1 | 0 |
| **Wound drainage applications per study participant** |  |  |
| Mean (SD) | 1 (NA) | NA |
| Min – Max | 1 – 1 |  |
| **Time expenditure per study participant, minutes**  Mean (SD)  Min – Max | 3 (NA)  3 – 3 | NA |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  | NA |
| Nursing auxiliary | 0 (0) |  |
| Nursing staff | 1 (3.0) |  |
| Assistant physician (resident) | 1 (3.0) |  |
| Specialist physician (consultant) | 1 (3.0) |  |
| **Number of study participants with other procedures** | 17 | 26 |
| **Other procedures per study participant** |  |  |
| Mean (SD) | 7.0 (13.6) | 5.5 (6.1) |
| Min – Max | 1 - 71 | 1 - 26 |
| **Time expenditure per study participant, minutes**  Mean (SD)  Min – Max | 7.7 (15.0)  1 – 105 | 7.0 (4.0)  1 – 15 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |
| Nursing auxiliary | 2 (105.0) | 7 (9.4) |
| Nursing staff | 110 (5.1) | 113 (7.8) |
| Assistant physician (resident) | 25 (17.7) | 20 (8.5) |
| Specialist physician (consultant) | 7 (37.6) | 11 (9.1) |

**eTable 15: Demographics, baseline health economic parameters and wound characteristics of the ITT study population**

|  |  |  |
| --- | --- | --- |
| **Randomized treatment arms** | **NPWT** | **CWT** |
| **Study participants in the ITT population,** No. | **256** | **251** |
| **Age in years,** Median (IQR) [Min-Max] | 66 (18) [21-88] | 66 (20) [26-91] |
| **Sex No. (%)** |  |  |
| Male | 155 (60.5) | 132 (52.6) |
| Female | 101 (39.5) | 119 (47.4) |
| **Marital status No.** |  |  |
| Single | 36 | 37 |
| Cohabiting | 24 | 16 |
| Married | 137 | 151 |
| Divorced | 25 | 14 |
| Widowed | 33 | 32 |
| Other | 2 | 1 |
| **Number of children** |  |  |
| Mean (SD) | 1.6 (1.3) | 1.6 (1.2) |
| Min-Max | 0-8 | 0-7 |
| **Wound surface area at randomization** **calculated from CRF entries (width and length) with imputed data** |  |  |
| Study participants with data available, No. | 256 | 251 |
| Mean (SD) | 27.5 (32.7) | 27.0 (30.5) |
| Min-Max | 0-345 | 1-208 |
| **Wound volume at randomization calculated from CRF entries (width, length and depth) with imputed data** |  |  |
| Study participants with data available, No. | 256 | 250 |
| Mean (SD) | 102.6 (173.4) | 104.4 (159.8) |
| Min-Max | 0-2070.0 | 0.6-1520.0 |
| **Location prior to hospitalization** **No.** |  |  |
| Home | 226 | 227 |
| Hospital | 24 | 20 |
| Institutional care facility | 1 | 3 |
| Retirement home | 1 | 1 |
| Other | 4 | 1 |
| **Reason for initial hospitalization** **No.** |  |  |
| Elective surgery | 131 | 130 |
| Diagnostic procedure | 10 | 7 |
| Acute setting | 60 | 52 |
| Emergency | 57 | 62 |
| **Hospitalization time prior to screening (days)** |  |  |
| Mean (SD) | 12 (9) | 12 (10) |
| Min-Max | 0-71 | 0-81 |
| **Mobility status** **No.** |  |  |
| Bedridden or mobilized in a wheel chair | 12 | 13 |
| Able to move freely within home | 30 | 29 |
| Able to leave home | 214 | 211 |
| **Leisure activities** **No.** |  |  |
| Indoor activities | 61 | 63 |
| Outdoor activities | 172 | 142 |
| Recreational sports | 43 | 63 |
| Competitive sports | 2 | 2 |
| **Employment status** **No.** |  |  |
| Unemployed\* | 16 | 9 |
| Seeking work+ | 4 | 5 |
| Apprenticeship | 0 | 0 |
| Student | 1 | 1 |
| Full-time worker | 64 | 55 |
| Part-time worker | 6 | 19 |
| Casual worker | 0 | 1 |
| Probationary time | 0 | 0 |
| Fixed term worker | 0 | 0 |
| Welfare recipient | 1 | 2 |
| Pensioner | 154 | 153 |
| Other | 13 | 10 |
| **Occupational activity, if participant was working** **No.** |  |  |
| Sedentary work | 20 | 23 |
| Light physical work | 16 | 11 |
| Medium physical work | 27 | 30 |
| High physical work | 13 | 15 |

*\*+Both “unemployed” and “seeking work” was reported for two study participants. For one study participant both “Employment status: Other = Housewife” and “unemployed” was reported.*

**eTable 16: Last and final wound pretreatment procedure (debridement or procedure for thorough wound cleansing) required before initiation of study treatment (documented during randomization visit) in the ITT population**

|  |  |  |
| --- | --- | --- |
| **Randomized treatment arms** | **NPWT** | **CWT** |
| **Study participants in the ITT population,** No. | **256** | **251** |
| **Location**  Study participants with information available No.  Bedside  Treatment room  Operation theatre  Other | 220  174  29  16  1 | 216  175  31  9  1 |
| **Anesthesia performed**  Study participants with information available No.  Number of study participants with anesthesia performed  Local anesthesia  Regional anesthesia – Peripheral nerve blocks  Regional anesthesia – Epidural and spinal anesthesia  General anesthesia  Number of study participants without anesthesia performed | 219  27  8  2  0  18  192 | 216  11  2  1  0  9  205 |
| **Overall expenditure of time, minutes**  Study participants with information available No.  Mean (SD) [Min – Max] | 211  16.8 (15.8) [1 – 126] | 203  15.7 (16.5) [2 – 177] |
| **Performed procedures\***  Study participants with information available No.  Wound cleansing  Wound lavage  Sharp debridement  Surgical debridement  Autolytic debridement  Biological debridement  Enzymatic debridement  Mechanical debridement  Application of wound drainage  Other | 217  184  109  37  15  0  0  1  19  8  47 | 212  182  102  24  8  2  0  2  27  4  54 |
| **Human resources**  **Nursing auxiliary**  Study participants with human resource use No.  Number of persons involved  Mean (SD) [Min-Max]  Expenditure of time, minutes  Study participants with information available No.  Mean (SD)  [Min-Max]  **Nursing staff**  Study participants with human resource use No.  Number of persons involved  Mean (SD) [Min-Max]  Expenditure of time  Study participants with information available No.  Mean (SD)  [Min-Max]  **Physician**  Study participants with human resource use No.  Number of persons involved  Mean (SD) [Min-Max]  Expenditure of time  Study participants with information available No.  Mean (SD)  Min-Max  **Other** Study participants with human resource use No. | 20  20  1.1 [1-2]  20  34.5 (48.5)  [2-174]  118  117  1.1 (0.3) [1-2]  114  19.9 (25.0)  [2-174]  196  195  1.2 (0.6) [1-4]  193  16.5 (17.7)  1-174  8 | 26  28  1.1 [1-2]  28  15.0 (18.9)  [2-105]  103  103  1.1 (0.4) [1-3]  98  20.9 (41.5)  [1-360]  179  178  1.1 (0.3) [1-3]  174  17.9 (34.0)  1-360  12 |

\*Multiple answers possible

**eTable 17: Wound closure by secondary intention and surgical wound closure procedure in the ITT population**

|  |  |  |
| --- | --- | --- |
| **Randomized treatment arms** | **NPWT** | **CWT** |
| **Study participants in the ITT population,** No. | 256 | 251 |
| Number of study participants with wound closure by secondary intention and surgical wound closure documented (both with date) \* | 3 | 6 |
| Number of study participants with wound closure within 42 days but without closure type documented | 0 | 4 |
| Number of study participants with wound closure and/or wound closure confirmation visit performed after day 42 | 3 | 6 |
| **Number of study participants with wound closure by secondary intention within 42 days (with date documented)** | **32** | **34** |
| Number of study participants with wound closure by secondary intention during inpatient care | 3 | 4 |
| Number of study participants with wound closure by secondary intention during outpatient care | 29 | 30 |
| Number of study participants with wound closure by secondary intention with invalid date documented (assignment to in- or outpatient care impossible) | 0 | 1 |
| **Number of study participants with surgical wound closure (with date documented)** | **97** | **37** |
| Number of study participants with surgical wound closure during inpatient care | 71 | 21 |
| Number of study participants with surgical wound closure during outpatient care | 26 | 16 |
| Number of study participants with surgical wound closure without date documented (assignment to in- or outpatient care impossible) | 1 | 0 |
| **Number of study participants with surgical wound closure procedure documented** | 104 | 45 |
| **Location**  Bedside  Treatment Room  Operation Theatre  Other | 25  32  43  1 | 11  18  15  1 |
| **Anesthesia performed**  Yes  Local anesthesia  Regional anesthesia - Peripheral nerve blocks  Regional anesthesia - Epidural and spinal anesthesia  General anesthesia  No | 75  29  1  0  44  37 | 30  16  1  0  13  30 |
| **Overall expenditure of time, minutes**  Mean (SD)  Min-Max | 24 (17)  2-90 | 27 (21)  5-90 |
| **Performed procedures (N)** |  |  |
| Wound cleansing | 51 | 32 |
| Wound lavage | 22 | 19 |
| Sharp Debridement | 3 | 2 |
| Surgical Debridement (in the operating theatre) | 11 | 8 |
| Autolytic Debridement | 1 | 0 |
| Biological Debridement (larval (maggot) therapy) | 0 | 0 |
| Enzymatic Debridement | 0 | 0 |
| Mechanical Debridement | 2 | 0 |
| Application of wound drainage | 15 | 10 |
| Secondary Suture | 78 | 37 |
| Skin Graft | 0 | 0 |
| Flap | 0 | 0 |
| Other | 18 | 9 |
| **Human Resources** |  |  |
| **Number of procedures with nursing auxiliary** | 13 | 7 |
| **Personnel expenditure No.** | 13 | 7 |
| Mean (SD) | 1 (0) | 1 (0) |
| Min-Max | 1-1 | 1-1 |
| **Time expenditure, minutes** |  |  |
| Study participants with information available No. | 12 | 7 |
| Mean (SD) | 45 (33) | 45 (34) |
| Min-Max | 10-100 | 5-92 |
| **Number of procedures with nursing staff** | 75 | 30 |
| **Personnel expenditure No.** | 102 | 39 |
| Mean (SD) | 1 (1) | 1 (1) |
| Min-Max | 1-4 | 1-3 |
| **Time expenditure, minutes** |  |  |
| Study participants with information available No. | 74 | 30 |
| Mean (SD) | 29 (28) | 30 (24) |
| Min-Max | 2-145 | 5-92 |
| **Number of procedures with physician** | 97 | 42 |
| **Personnel expenditure No.** | 125 | 55 |
| Mean (SD) | 1 (1) | 1 (1) |
| Min-Max | 1-4 | 1-4 |
| **Time expenditure, minutes** |  |  |
| Study participants with information available No. | 95 | 42 |
| Mean (SD) | 26 (24) | 26 (30) |
| Min-Max | 2-140 | 5-180 |
| **Number of procedures with other human resources used** | 13 | 6 |
| Anesthesiologist | 8 | 3 |
| Anesthesiologist in Stand-by | 1 | 0 |
| Intern | 1 | 3 |
| Medical student in practical year | 1 | 0 |
| Resident physician | 1 | 0 |
| Senior physician | 1 | 0 |

\*Because of the documentation of both, surgical wound closures and wound closures by secondary intention, no clear allocation to care sectors is possible for these study participants. #For one study participants with surgical wound closure during outpatient care within 42 days, wound closure was only documented during the follow up.

**eTable 18: Care status and treatment periods during the active study treatment time of 42 days in the ITT population**

|  |  |  |  |
| --- | --- | --- | --- |
| **Randomized treatment arms / Statistical significance** | **NPWT** | **CWT** | **p**  **(test used)** |
| **Study participants in the ITT population,** No. | 256 | 251 | NA |
| **Length of treatment (days)**  Mean (SD)  Min-Max | 22.8 (13.4)  3 - 42 | 30.6 (13.3)  2 - 42 | <.001 |
| **Number of study participants treated with NPWT** | 255 (99.6%) | 50 (19.9%) | NA |
| **Length of NPWT (days)**  Mean (SD) [95% CI]  Min-Max | 15.0 (9.2)  1 – 42 | 16.6 (9.8)  3 - 39 | NA |
| **Number of study participants treated with CWT** | 112 | 247 | NA |
| **Length of CWT (days)**  Mean (SD) [95% CI]  Min-Max | 19.9 (10.2)  1 – 42 | 26.5 (14.7)  1 – 42 | NA |
| **Study participants with inpatient study start No. (%)** | 236 (92.2%) | 226 (90.0%) | NA |
| **Study participants exclusively treated in hospital No. (%)** | 45 (17.6%) | 27 (10.8%) | NA |
| **Length of hospital stay for study participants exclusively treated inpatient** |  |  |  |
| Mean (SD)  Min-Max | 28.4 (10.8)  8-42 | 27.5 (14.1)  7-42 | NA |
| **Study participants with inpatient care N (%)** | 236 (92.2%) | 229 (91.2%) | .697 (C) |
| **Length of hospital stay (days)** | 15.1 (11.5)  0 – 42 | 13.9 (11.7)  0 – 42 |  |
| Mean (SD) Min-Max | .119 (U) |
| **Length of hospital stay excluding study participants exclusively treated inpatient including study participants with outpatient study start** |  |  |  |
| N  Mean (SD)  Min-Max | 211  12.3 (9.4)  0-40 | 224  13.3 (10.3)  0-41 | .635 (U) |
| **Study participants with inpatient NPWT N** | 235 | 44 | NA |
| **Length of inpatient NPWT** |  |  |  |
| Mean (SD) | 11.1 (7.2) | 12.9 (8.9) | NA |
| Min-Max | 1 - 36 | 1 - 39 |  |
| **Study participants with inpatient CWT N** | 65 | 227 | NA |
| **Length of inpatient CWT (days)** |  |  |  |
| Mean (SD) | 8.9 (6.9) | 11.3 (9.4) | NA |
| Min-Max | 1 - 29 | 1 - 42 |  |
| **Study participants with study start in hospital and discharged until end of study treatment period of 42 days** | 191 (74.6%) | 199 (79.3%) | NA |
| **Time until first discharge from hospital during the study treatment period of 42 days** |  |  |  |
| Mean (SD) | 13.3 (8.5) | 13.1 (8.7) | .42 (U) |
| Min-Max | 2 - 41 | 2 – 42 |
| **Study participants with outpatient study start** **N (%)** | 20 (7.8%) | 25 (10.0%) | NA |
| **Number of study participants exclusively treated outpatient** **N (%)** | 20 (7.8%) | 22 (8.8%) | NA |
| **Study participants with outpatient care** **N (%)** | 211 (82.4%) | 224 (89.2%) | .028 (C) |
| **Length of outpatient care (days)** |  |  |  |
| Mean (SD) | 17.8 (13.2) | 22.3 (13.6) | <.001 (U) |
| Min-Max | 0 – 42 | 0 – 42 |
| **Study participants with outpatient NPWT N** | 94 | 14 | NA |
| **Length of outpatient NPWT (days)** |  |  |  |
| Mean (SD) | 12.7 (9.2) | 18.1 (9.8) | NA |
| Min-Max | 1 - 42 | 2 - 36 |  |
| **Study participants with outpatient CWT N** | 91 | 169 | NA |
| **Length of outpatient CWT (days)** |  |  |  |
| Mean (SD) | 18.1 (10.1) | 23.5 (11.9) | NA |
| Min-Max | 1 - 39 | 1 - 42 |
| **Number of study participants with hospital readmission during the active study treatment time of 42 days No. (%)** | 59 (11.6%) | 29 (11.3%) | .827 (C) |
| **Number of study participants still under treatment at day 42 No. (%)** | 102 (39.8%) | 146 (58.2%) | NA |

C = Chi-squared test; U = Mann-Whitney U-Test

**eTable 19: Time and human resources required for dressing changes in the ITT population**

|  |  |  |  |
| --- | --- | --- | --- |
| **Randomized treatment arms / Statistical significance** | **NPWT** | **CWT** | **P**  **(test)** |
| **Study participants in the ITT population,** No. | **256** | **251** | **NA** |
| **Number of dressing changes per study participant** |  |  |  |
| Study participants with data available, No. | 214 | 213 | <.001  (U test) |
| Mean (SD) | 10.1 (9.2) | 19.5 (12.8) |
| Min - Max | 1 - 80 | 1 - 78 |
| **Time required for dressing changes per study participant, minutes** |  |  |  |
| Number study participants with data available | 213 | 213 | <.001  (U test) |
| Mean (SD) | 179.5 (186.7) | 288.8 (263.4) |
| Min - Max | 5 - 2098 | 10 - 2821 |
| **Physician contacts for dressing changes** |  |  | .001  (U test) |
| Study participants with data available, No. | 201 | 184 |
| Mean (SD) | 5.8 (4.2) | 8.3 (7.3) |
| Min - Max | 1 - 25 | 1 - 42 |
| **Physician`s time per study participant, minutes** |  |  |  |
| Study participants with data available, No. | 200 | 184 | .537  (U test) |
| Mean (SD) | 114.6 (90.3) | 135.0 (137.1) |
| Min - Max | 5.0 – 536.0 | 1.0 – 1181.0 |
| **Nurse contacts for dressing changes** |  |  |  |
| Study participants with data available, No. | 181 | 183 | <.001  (U test) |
| Mean (SD) | 7.7 (8.5) | 14.2 (10.8) |
| Min - Max | 1 - 79 | 1 - 72 |
| **Nurse`s time per study participant, minutes** |  |  |  |
| Study participants with data available, No. | 179 | 183 | <.001  (U test) |
| Mean (SD) | 145.2 (179.1) | 222.9 (187.5) |
| Min - Max | 5.0 – 2086.0 | 5.0 – 1238.0 |
| **Nursing assistance contacts for dressing changes** |  |  |  |
| Study participants with data available, No. | 29 | 32 | .897  (U test) |
| Mean (SD) | 2.8 (2.3) | 3.3 (3.7) |
| Min - Max | 1 - 9 | 1 - 16 |
| **Nursing assistance`s time per study participant, minutes** |  |  |  |
| Study participants with data available, No. | 28 | 32 | .106  (U test) |
| Mean (SD) | 68.3 (46.6) | 60.2 (70.9) |
| Min - Max | 10.0 -180.0 | 5.0 – 280.0 |
| **Relatives contacts for dressing changes** |  |  |  |
| Study participants with data available, No. | 15 | 41 | .430  (U test) |
| Mean (SD) | 8.3 (8.8) | 11.2 (12.1) |
| Min - Max | 1 - 26 | 1 - 62 |
| **Relative`s time per study participant, minutes** |  |  |  |
| Study participants with data available, No. | 14 | 40 | .730  (U test) |
| Mean (SD) | 119.9 (145.1) | 129.7 (163.1) |
| Min - Max | 5.0 – 500.0 | 5.0 – 840.0 |
| **Number of inpatient dressing changes per study participant** |  |  |  |
| Study participants with data available, No. | 194 | 183 | <.001  (U test) |
| Mean (SD) | 6.0 (5.8) | 10.7 (9.5) |
| Min - Max | 1.0 – 48.0 | 1.0 – 71.0 |
| **Time required for inpatient dressing changes per study participant, minutes** |  |  |  |
| Number study participants with data available | 192 | 183 | .009  (U test) |
| Mean (SD) | 111.5 (109.3) | 159.8 (236.4) |
| Min - Max | 10.0 – 951.0 | 5.0 – 2821.0 |
| **Number of outpatient dressing changes per study participant** |  |  |  |
| Study participants with data available, No. | 120 | 149 | <.001  (U test) |
| Mean (SD) | 8.3 (9.5) | 14.7 (11.9) |
| Min - Max | 1.0 – 78.0 | 1.0 – 78.0 |
| **Time required for outpatient dressing changes per study participant, minutes** |  |  |  |
| Number study participants with data available | 119 | 149 | <.001  (U test) |
| Mean (SD) | 141.2 (209.2) | 216.6 (182.9) |
| Min - Max | 5.0 - 2053.0 | 3.0 – 888.0 |

U = Mann-Whitney U-Test

**eTable 20: Time and human resources required for NPWT dressing changes in the ITT population**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Randomized treatment arms** | **Inpatient NPWT** | **Inpatient CWT** | **Outpatient NPWT** | **Outpatient CWT** |
| **Study participants in the ITT population,** No. | 256 | 251 | 256 | 251 |
| **Number of study participants with NPWT** | 235 | 44 | 100 | 14 |
| **Number of inpatient NPWT dressing changes per study participant** |  |  |  |  |
| Study participants with data available No. | 193 | 33 | 79 | 11 |
| Mean (SD) | 4.5 (3.2) | 5.6 (6.7) | 4.9 (5.0) | 6.8 (4.6) |
| Min - Max | 1.0 - 20.0 | 1.0 – 39.0 | 1-36 | 1-19 |
| **Time required per inpatient NPWT dressing change** |  |  |  |  |
| Dressing changes with time recording No. | 849 | 180 | 380 | 75 |
| Mean (SD) | 21.5 (16.2) | 36.5 (29.6) | 22.0 (13.8) | 24.2 (8.3) |
| Min - Max | 1 - 150 | 5 - 134 | 2 - 97 | 12 - 50 |
| **Time required for inpatient NPWT dressing changes per study participant** |  |  |  |  |
| Study participants with data available No. | 191 | 33 | 79 | 11 |
| Mean (SD) | 95.7 (97.7) | 198.9 (480.1) | 106.0 (116.2) | 164.8 (118.7) |
| Min - Max | 10.0-951.0 | 15.0-2821.0 | 10.0-751.0 | 18.0-488.0 |
| **Physician contacts for inpatient NPWT dressing change** |  |  |  |  |
| Study participants with data available No. | 174 | 32 | 65 | 11 |
| Mean (SD) | 3.9 (2.7) | 4.0 (3.1) | 3.5 (3.0) | 5.7 (5.1) |
| Min – Max | 1 - 16 | 1 - 16 | 1 - 16 | 1 - 19 |
| **Physician`s time per study participant, minutes** |  |  |  |  |
| Study participants with data available No. | 172 | 32 | 65 | 11 |
| Mean (SD) | 22.0 (16.6) | 34.7 (27.9) | 21.7 (13.7) | 24.4 (8.9) |
| Min – Max | 1 – 150 | 5 – 134 | 2 - 94 | 12 - 50 |
| **Nurse contacts for inpatient NPWT dressing change** |  |  |  |  |
| Study participants with data available No. | 151 | 27 | 58 | 10 |
| Mean (SD) | 3.4 (2.4) | 3.7 (3.6) | 4.3 (5.0) | 5.6 (2.2) |
| Min – Max | 1 - 16 | 1 - 19 | 1 - 36 | 3 - 9 |
| **Nurse`s time per study participant, minutes** |  |  |  |  |
| Study participants with data available No. | 150 | 27 | 58 | 10 |
| Mean (SD) | 22.6 (17.2) | 34.7 (27.5) | 23.4 (13.9) | 24.1 (8.6) |
| Min – Max | 1 – 150 | 5 – 134 | 3 - 97 | 15 - 50 |
| **Nursing assistance contacts for dressing change** |  |  |  |  |
| Study participants with data available No. | 20 | 6 | 5 | 1 |
| Mean (SD) | 2.6 (2.1) | 4.0 (4.0) | 2.6 (2.1) | 2.0 (NA) |
| Min – Max | 1 - 7 | 1 - 9 | 1 - 6 | 2 - 2 |
| **Nursing assistance`s time per study participant, minutes** |  |  |  |  |
| Study participants with data available No. | 20 | 6 | 5 | 1 |
| Mean (SD) | 27.0 (18.4) | 31.1 (27.0) | 22.3 (19.5) | 20.0 (0) |
| Min – Max | 6 – 110 | 10 – 105 | 10 - 80 | 20 - 20 |
| **Relative contacts for dressing change** |  |  |  |  |
| Study participants with data available No. | 1 | 0 | 3 | 1 |
| Mean (SD) | 1.0 (NA) | NA | 5.3 (4.9) | 1.0 (NA) |
| Min – Max | 1 – 1 | NA | 2 - 11 | 1 - 1 |
| **Relative`s time per study participant, minutes** |  |  |  |  |
| Study participants with data available No. | 1 | 0 | 3 | 1 |
| Mean (SD) | 100.0 (NA) | NA | 27.5 (4.1) | 30.0 (NA) |
| Min – Max | 100 – 100 | NA | 20 - 30 | 30 - 30 |

**eTable 21: Time and human resources required for CWT dressing changes in the ITT population**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Randomized treatment arms** | **Inpatient NPWT** | **Inpatient CWT** | **Outpatient NPWT** | **Outpatient CWT** |
| **Study participants in the ITT population,** No. | 256 | 251 | 256 | 251 |
| **Number of study participants with inpatient CWT** | 7 | 225 | 1\* | 174 |
| **Number of inpatient NPWT dressing changes per study participant** |  |  |  |  |
| Study participants with data available No. | 3 | 179 | 0 | 143 |
| Mean (SD) | 3.3 (2.5) | 9.9 (9.4) | NA | 14.8 (12.1) |
| Min - Max | 1-6 | 1-71 |  | 1-78 |
| **Time required per inpatient CWT dressing change** |  |  |  |  |
| Number of dressing changes with time recording | 10 | 1712 | 0 | 2042 |
| Mean (SD) | 11.6 (7.7) | 13.3 (7.3) | NA | 14.9 (8.3) |
| Min - Max | 1 - 20 | 1 - 65 |  | 1 - 90 |
| **Time required for inpatient CWT dressing changes per study participant** |  |  |  |  |
| Study participants with data available No. | 3 | 179 | 0 | 143 |
| Mean (SD) | 38.7 (20.1) | 126.7 (122.0) | NA | 213.0 (182.2) |
| Min - Max | 20 – 60 | 5 – 765 |  | 3 – 888 |
| **Physician contacts for dressing change** |  |  |  |  |
| Study participants with data available No. | 1 | 145 | 0 | 104 |
| Mean (SD) | 3 (NA) | 5.8 (6.7) | NA | 4.9 (5.6) |
| Min - Max | 3 - 3 | 1 - 42 |  | 1 - 39 |
| **Physician`s time per study participant, minutes** |  |  |  |  |
| Study participants with data available No. | 1 | 144 | 0 | 11 |
| Mean (SD) | 5.3 (4.5) | 14.0 (8.5) | NA | 24.4 (8.9) |
| Min - Max | 1 - 10 | 1 - 60 |  | 12 - 50 |
| **Nurse contacts for dressing change** |  |  |  |  |
| Study participants with data available No. | 3 | 146 | 0 | 118 |
| Mean (SD) | 3.0 (2.0) | 7.7 (8.6) | NA | 11.2 (8.8) |
| Min - Max | 1 - 5 | 1 - 71 |  | 1 - 38 |
| **Nurse`s time per study participant, minutes** |  |  |  |  |
| Study participants with data available No. | 3 | 146 | 0 | 118 |
| Mean (SD) | 12.8 (7.1) | 13.5 (7.0) | NA | 16.7 (8.6) |
| Min - Max | 5 - 20 | 2 - 65 |  | 1 - 90 |
| **Nursing assistance contacts for dressing change** |  |  |  |  |
| Study participants with data available No. | 0 | 24 | 0 | 6 |
| Mean (SD) | NA | 2.5 – 2.1 | NA | 3.2 (2.6) |
| Min - Max | NA | 1 - 9 |  | 1 - 8 |
| **Nursing assistance`s time per study participant, minutes** |  |  |  |  |
| Study participants with data available No. | 0 | 24 | 0 | 6 |
| Mean (SD) | NA | 13.5 (7.4) | NA | 18.2 (8.5) |
| Min - Max | NA | 3 - 57 |  | 10 - 40 |
| **Relative contacts for dressing change** |  |  |  |  |
| Study participants with data available No. | 0 | 5 | 0 | 39 |
| Mean (SD) | NA | 7.0 (12.3) | NA | 10.8 (12.0) |
| Min - Max | NA | 1 - 29 |  | 1 - 62 |
| **Relative`s time per study participant, minutes** |  |  |  |  |
| Study participants with data available No. | 0 | 5 | 0 | 38 |
| Mean (SD) | NA | 10.4 (3.5) | NA | 11.7 (6.8) |
| Min - Max | NA | 5 - 30 |  | 1 - 60 |

\*Clinical investigators indicated that outpatient CWT dressing changes (that were not post NPWT CWT dressing changes) were performed in one study participant in the NPWT arm, but without documenting further details.

**eTable 22: Time and human resources required for dressing changes during the inpatient and outpatient post NPWT CWT period in the ITT population**

|  |  |  |
| --- | --- | --- |
| **Treatment sectors** | **Inpatient** | **Outpatient** |
| **Study participants in the ITT population,** No. | 256 | 256 |
| **Number of study participants post NPWT CWT period** | 56 | 92 |
| **Number of inpatient NPWT dressing changes per study participant** |  |  |
| Study participants with data available, No. | 45 | 74 |
| Mean (SD) | 6.4 (7.1) | 8.3 (8.7) |
| Min - Max | 1-42 | 1-42 |
| **Time required per inpatient CWT dressing change** |  |  |
| Number of dressing changes with time recording | 276 | 580 |
| Mean (SD) | 10.9 (8.7) | 14.6 (9.8) |
| Min - Max | 1-95 | 1-100 |
| **Time required for inpatient CWT dressing changes per study participant** |  |  |
| Study participants with data available, No. | 43 | 73 |
| Mean (SD) | 70.2 (75.4) | 115.5 (172.7) |
| Min - Max | 5.0 – 351.0 | 5.0 – 1302.0 |
| **Physician contacts for dressing change** |  |  |
| Study participants with data available, No. | 30 | 49 |
| Mean (SD) | 3.9 (3.5) | 2.7 (1.7) |
| Min - Max | 1 - 12 | 1 - 7 |
| **Physician`s time per study participant, minutes** |  |  |
| Study participants with data available, No. | 29 | 48 |
| Mean (SD) | 13.0 (11.5) | 15.4 (11.5) |
| Min - Max | 1 - 95 | 1 - 70 |
| **Nurse contacts for dressing change** |  |  |
| Study participants with data available, No. | 34 | 59 |
| Mean (SD) | 6.2 (7.6) | 7.1 (7.5) |
| Min - Max | 1 - 40 | 1 - 41 |
| **Nurse`s time per study participant, minutes** |  |  |
| Study participants with data available, No. | 32 | 57 |
| Mean (SD) | 11.3 – 9.7 | 15.7 (10.9) |
| Min - Max | 1 - 95 | 1 - 100 |
| **Nursing assistance contacts for dressing change** |  |  |
| Study participants with data available, No. | 5 | 5 |
| Mean (SD) | 1.2 (0.5) | 2.0 (2.2) |
| Min - Max | 1 - 2 | 1 - 6 |
| **Nursing assistance`s time per study participant, minutes** |  |  |
| Study participants with data available, No. | 5 | 4 |
| Mean (SD) | 32.5 (32.4) | 18.8 (10.3) |
| Min - Max | 10 - 95 | 10 - 30 |
| **Relative contacts for dressing change** |  |  |
| Study participants with data available, No. | 0 | 11 |
| Mean (SD) | NA | 9.8 – 9.6 |
| Min - Max | NA | 1 - 26 |
| **Relative`s time per study participant, minutes** |  |  |
| Study participants with data available, No. | 0 | 10 |
| Mean (SD) | NA | 12.1 (5.4) |
| Min - Max | NA | 5 - 20 |

**eTable 23: Dressing material and wound dressing use during in- and outpatient care in the ITT population**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Randomized treatment arms** | **… during inpatient care in the NPWT arm** | **… during inpatient care in the CWT arm** | **… during outpatient care in the NPWT arm** | **… during outpatient care in the CWT arm** |
| **Study participants in the ITT population,** No. | **256** | **251** | **256** | **251** |
| **Number of study participants with dressing material use (which was used for fixation, cushioning and absorption of liquid, but was not directly placed on the wound)** | **163 of 170** | **166 of 167** | **163 of 170** | **166 of 167** |
| Sterile compresses | 156 | 161 | 105 | 139 |
| Stretch bandages | 56 | 111 | 48 | 88 |
| Fixation material / patch / plaster/ strip / tape | 28 | 35 | 48 | 64 |
| Absorbent dressings | 16 | 56 | 18 | 43 |
| Unsterile compresses | 15 | 25 | 12 | 20 |
| Swabs | 16 | 13 | 11 | 20 |
| Unsterile film | 9 | 16 | 12 | 12 |
| Sterile film | 16 | 10 | 10 | 6 |
| Bandage gauze | 5 | 10 | 9 | 7 |
| Self-adhesive non-woven (fleece) dressings | 0 | 3 | 3 | 4 |
| Abdominal bandages | 2 | 4 | 1 | 2 |
| Pads / mats / plates | 3 | 4 | 0 | 2 |
| Superabsorber | 2 | 2 | 1 | 3 |
| Antimicrobial dressings | 0 | 3 | 1 | 3 |
| Sets / kits | 1 | 2 | 0 | 2 |
| Drug-free ointment dressings | 0 | 0 | 2 | 0 |
| Abdominal cloths | 0 | 0 | 0 | 2 |
| Foam dressings | 0 | 1 | 0 | 0 |
| Other material without or with unidentifiable description | 6 | 14 | 10 | 14 |
| **Number of study participants with wound dressing use documented** | **78 of 170** | **121 of 167** | **78 of 170** | **121 of 167** |
| Antimicrobial dressings | 12 | 51 | 14 | 42 |
| Alginate without silver | 16 | 40 | 14 | 31 |
| Soft-adhesive foam bandages without silver | 7 | 22 | 15 | 24 |
| Self-adhesive foam bandages without silver | 6 | 16 | 12 | 27 |
| Self-adhesive non-woven (fleece) dressings | 9 | 11 | 12 | 17 |
| Hydrofiber with silver | 4 | 20 | 4 | 20 |
| Hydrocolloid without silver | 12 | 7 | 16 | 8 |
| Hydrofiber without silver | 2 | 14 | 1 | 22 |
| Film transparent | 7 | 13 | 8 | 8 |
| Alginate with silver | 4 | 18 | 1 | 10 |
| Composites without silver | 1 | 12 | 3 | 9 |
| Non-adhesive foam | 5 | 8 | 2 | 8 |
| Abdominal cloths | 15 | 7 | 0 | 0 |
| Superabsorber | 0 | 13 | 1 | 8 |
| Absorbent dressings | 1 | 5 | 2 | 9 |
| Plaster / patches / strips | 8 | 7 | 1 | 1 |
| Mesh | 6 | 4 | 0 | 1 |
| Gauze without silver | 0 | 4 | 1 | 5 |
| Composites with silver | 2 | 4 | 0 | 2 |
| Active coal compresses | 0 | 4 | 1 | 2 |
| Silicone dressings | 1 | 0 | 2 | 2 |
| Soft-adhesive Foam bandages with silver | 0 | 2 | 0 | 2 |
| Self-adhesive foam bandages with silver | 0 | 1 | 1 | 1 |
| Collagen with silver | 0 | 1 | 0 | 1 |
| Hydrogel | 0 | 0 | 1 | 1 |
| Transparent film with silver | 0 | 1 | 0 | 0 |
| Hydrocolloid with silver | 0 | 1 | 0 | 0 |
| Non-woven non adhesive dressings / fleece compresses | 0 | 1 | 0 | 0 |
| Medical honey | 0 | 0 | 1 | 0 |
| Gauze with silver | 0 | 0 | 0 | 0 |
| Collagen without silver | 0 | 0 | 0 | 0 |
| Other material without or with unidentifiable description | 5 | 11 | 8 | 9 |

**eTable 24: Wound-related procedures performed during the active study treatment time of 42 days in the ITT population**

|  |  |  |  |
| --- | --- | --- | --- |
| **Randomized treatment arms / Statistical significance** | **NPWT** | **CWT** | **p**  **(test used)** |
| **Study participants in the ITT population,** No. | **256** | **251** | **NA** |
| **Total number of wound related procedures** | 5126 | 8415 | NA |
| **Wound related procedures per study participant** |  |  |  |
| Mean (SD) | 20.0 (16.8) | 33.5 (27.2) | <0.001 |
| Min – Max | 0 – 124 | 0 – 174 | (U test) |
| **Total time expenditure per study participant, minutes** |  |  |  |
| Mean (SD)  Min – Max | 173 (192)  0 – 1060 | 268 (305)  0 – 2019 | <0.001  (U test) |
| **Total time expenditure for nursing auxiliary, minutes per study participant** |  |  |  |
| Mean (SD) | 12 (49) | 22 (99) | 0.086 |
| Min - Max | 0 – 480 | 0 – 1263 | (U test) |
| **Total time expenditure for nursing staff, minutes per study participant, minutes** |  |  |  |
| Mean (SD) | 116 (178) | 172 (243) | 0.009 |
| Min - Max | 0 – 1060 | 0 – 1466 | (U test) |
| **Total time expenditure for assistant physician, minutes per study participant** |  |  |  |
| Mean (SD) | 77 (130) | 83 (157) | 0.259 |
| Min - Max | 0 – 920 | 0 – 1365 | (U test) |
| **Total time expenditure specialist physician, minutes per study participant** |  |  |  |
| Mean (SD) | 54 (115) | 50 (108) | 0.198 |
| Min - Max | 0 – 893 | 0 – 802 | (U test) |
| **Total number of inpatient wound related procedures** | 2630 | 4065 | NA |
| **Inpatient wound related procedures per study participant** |  |  |  |
| Mean (SD) | 10.3 (12.9) | 16.2 (20.1) | NA |
| Min – Max | 0 – 124 | 0 – 119 |  |
| **Time expenditure per study participant, minutes** |  |  |  |
| Mean (SD)  Min – Max | 100 (142)  0 – 925 | 132 (205)  0 – 1340 | NA |
| **Total number of outpatients wound related procedures** | 2417 | 4213 | NA |
| **Outpatient wound related procedures per study participant** |  |  | NA |
| Mean (SD) | 9.4 (12.3) | 16.8 (20.4) |
| Min – Max | 0 – 57 | 0 – 155 |
| **Time expenditure per study participant, minutes** |  |  | NA |
| Mean (SD)  Min – Max | 69 (128)  0 – 990 | 132 (240)  0 – 1952 |
| **Total number of wound related procedures during the inpatient post NPWT CWT period** | 726 | NA | NA |
| **Number of study participants with inpatient post NPWT CWT period procedures** | 53 | NA | NA |
| **Inpatient post NPWT CWT period wound related procedures per study participant N** |  |  |  |
| Study participants with data available, No. | 53 | NA | NA |
| Mean (SD) | 13.7 (18.3) |  |  |
| Min – Max | 1 – 114 |  |  |
| **Time expenditure per study participant, minutes** |  |  |  |
| Study participants with data available, No. | 53 | NA | NA |
| Mean (SD) | 93 (138) |  |  |
| Min – Max | 2 – 890 |  |  |
| **Total number of wound related procedures during the outpatient post NPWT CWT period** | 1069 | NA | NA |
| **Number of study participants with outpatient post NPWT CWT period procedures** | 78 | NA | NA |
| **Outpatient post NPWT CWT period wound related procedures per study participant** |  |  |  |
| Study participants with data available, No. | 78 | NA | NA |
| Mean (SD) | 13.7 (10.6) |  |  |
| Min – Max | 1 – 47 |  |  |
| **Time expenditure per study participant, minutes** |  |  |  |
| Study participants with data available, No. | 77 | NA | NA |
| Mean (SD) | 101 (120) |  |  |
| Min – Max | 2 – 691 |  |  |

**eTable 25: Wound-related procedures performed during inpatient and outpatient care in the ITT population**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Randomized treatment arms** | **Inpatient**  **NPWT** | **Inpatient**  **CWT** | **Outpatient**  **NPWT** | **Outpatient**  **CWT** |
| **Study participants in the ITT population,** No. | **256** | **251** | **256** | **251** |
| **Study participants with wound cleansing,** No. | **193** | **194** | **152** | **185** |
| **Wound cleansings per study participant** |  |  |  |  |
| Mean (SD) | 5.5 (6.2) | 9.2 (9.2) | 8.1 (7.7) | 11.8 (11.8) |
| Min – Max | 1 - 48 | 1 - 48 | 1 - 56 | 1 - 77 |
| **Time expenditure per study participant, minutes** |  |  |  |  |
| Mean (SD)  Min – Max | 7.5 (8.3)  1 – 39 | 7.7 (8.4)  1 - 160 | 6.5 (5.8)  1 - 39 | 6.5 (5.6)  1 - 60 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary | 51 (10.0) | 114 (9.4) | 55 (7.8) | 225 (11.8) |
| Nursing staff | 626 (8.0) | 1235 (7.3) | 789 (7.4) | 1228 (7.9) |
| Assistant physician (resident) | 551 (9.0) | 687 (8.7) | 262 (6.9) | 401 (8.0) |
| Specialist physician (consultant) | 225 (9.6) | 333 (8.7) | 193 (6.8) | 287 (6.5) |
| **Study participants with wound lavage,** No. | **119** | **114** | **65** | **86** |
| **Wound lavage per study participant** |  |  |  |  |
| Mean (SD) | 4.3 (4.0) | 7.5 (7.9) | 5.3 (5.8) | 9.0 (9.0) |
| Min – Max | 1-26 | 1-42 | 1-31 | 1-35 |
| **Time expenditure per study participant, minutes** |  |  |  |  |
| Mean (SD)  Min – Max | 8.9 (14.7)  1 - 159 | 7.2 (7.0)  1 - 75 | 6.5 (6.5)  1 – 45 | 6.6 (7.5)  1 – 90 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary | 24 (22.2) | 42 (7.1) | 9 (11.4) | 51 (9.2) |
| Nursing staff | 258 (10.9) | 516 (7.4) | 187 (6.9) | 328 (7.7) |
| Assistant physician (resident) | 324 (9.6) | 384 (7.4) | 80 (6.9) | 207 (6.3) |
| Specialist physician (consultant) | 128 (17.1) | 121 (10.2) | 38 (5.5) | 73 (5.0) |
| **Study participants with sharp debridement (using scalpel or curette at bedside),** No. | **33** | **31** | **23** | **23** |
| **Sharp debridements per study participant** |  |  |  |  |
| Mean (SD) | 2.2 (1.7) | 2.7 (3.8) | 1.7 (1.0) | 2.2 (1.9) |
| Min – Max | 1 - 8 | 1 - 21 | 1 - 4 | 1 - 7 |
| **Time expenditure per study participant, minutes** |  |  |  |  |
| Mean (SD)  Min – Max | 11.4 (13.1)  1 – 62 | 9.0 (5.3)  2 – 25 | 9.9 (12.3)  1 – 50 | 6.4 (4.8)  1 – 20 |
| **Human Resources involved**, No. (M**ean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary | 8 (15.6) | 10 (5.6) | 1 (20.0) | 3 (14.7) |
| Nursing staff | 31 (13.l) | 19 (9.1) | 10 (7.9) | 17 (7.2) |
| Assistant physician (resident) | 57 (12.1) | 65 (8.8) | 20 (15.3) | 27 (7.4) |
| Specialist physician (consultant) | 22 (13.6) | 18 (12.4) | 12 (4.7) | 11 (5.7) |
| **Study participants with surgical debridement (in the operation theatre)** | **43** | **24** | **3** | **6** |
| **Surgical debridements per study participant,** No. |  |  |  |  |
| Mean (SD) | 2.4 (2.3) | 1.7 (1.1) | 1.3 (0.6) | 1.2 (0.4) |
| Min – Max | 1 - 10 | 1 - 5 | 1 - 2 | 1 - 2 |
| **Time expenditure per study participant, minutes** |  |  |  |  |
| Mean (SD)  Min – Max | 19.0 (16.9)  2 – 78 | 23.5 (30.6)  2 – 160 | 14.5 (7.6)  8 – 25 | 8.7 (6.4)  2 - 18 |
| **Human Resources involved**, No. (M**ean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary | 10 (28.7) | 3 (41.7) | 0 (0) | 0 (0) |
| Nursing staff | 71 (17.2) | 29 (26.5) | 4 (14.5) | 3 (10.3) |
| Assistant physician (resident) | 62 (17.3) | 28 (25.0) | 2 (20.0) | 1 (4.0) |
| Specialist physician (consultant) | 75 (19.6) | 36 (24.9) | 3 (14.3) | 6 (10.5) |
| **Study participants with autolytic debridement (Facilitation of the body`s own mechanisms of debridement with appropriate dressings),** No. | 4 | 7 | **5** | **8** |
| **Autolytic debridements per study participant** |  |  |  |  |
| Mean (SD) | 2.3 (1.9) | 7.0 (5.0) | 4.4 (4.3) | 4.5 (2.7) |
| Min – Max | 1 - 5 | 1 - 14 | 1 - 10 | 1 - 9 |
| **Time expenditure per study participant, minutes** |  |  |  |  |
| Mean (SD)  Min – Max | 11.7 (14.3)  1 – 30 | 2.7 (3.1)  1 – 14 | 5.2 (7.7)  1 – 30 | 2.2 (2.2)  1 – 10 |
| **Human Resources involved**, No. (M**ean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary | 1 (30.0) | 0 (0) | 4 (2.0) | 0 (0) |
| Nursing staff | 8 (6.1) | 49 (3.9) | 11 (7.5) | 36 (1.9) |
| Assistant physician (resident) | 1 (30.0) | 0 (0) | 0 (0) | 0 (0) |
| Specialist physician (consultant) | 1 (30.0) | 0 (0) | 1 (30.0) | 0 (0) |
| **Study participants with biological debridement (larval (maggot) therapy), No.** | **1** | **0** | **0** | **1** |
| **Biological debridements per study participant** |  |  |  |  |
| Mean (SD) | 1 (NA) | NA | NA | 1 (0) |
| Min – Max | 1-1 |  |  | 1 – 1 |
| **Time expenditure per study participant, minutes** |  |  |  |  |
| Mean (SD)  Min – Max | 58 (0)  58 - 58 | NA | NA | 10.0 (0)  10 – 10 |
| **Human Resources involved**, No. (M**ean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary | 0 (0) | NA | NA | 0 (0) |
| Nursing staff | 1 (58.0) |  |  | 0 (0) |
| Assistant physician (resident) | 0 (0) |  |  | 1 (10.0) |
| Specialist physician (consultant) | 0 (0) |  |  | 0 (0) |
| **Study participants with enzymatic debridement,** No. | **0** | **3** | **4** | **2** |
| **Enzymatic debridements per study participant** |  |  |  |  |
| Mean (SD) | NA | 3.1 (3.1) | 1.6 (1.3) | 1.3 (0.5) |
| Min – Max |  | 1 – 10 | 1- -4 | 1 - 2 |
| **Time expenditure per study participant, minutes** |  |  |  |  |
| Mean (SD)  Min – Max | NA | 24.1 (23.3)  7 – 78 | 7.8 (2.9)  3 – 10 | 5.0 (3.4)  3 – 10 |
| **Human Resources involved**, No. (M**ean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary | NA | 0 (0) | 0 (0) | 0 (0) |
| Nursing staff |  | 30 (29.2) | 6 (7.2) | 0 (0.0) |
| Assistant physician (resident) |  | 7 (57.4) | 1 (10.0) | 4 (5.0) |
| Specialist physician (consultant) |  | 0 (0) | 1 (10.0) | 1 (3.0) |
| **Study participants with mechanical debridement (wet-to-dry dressings),** No. | **19** | **32** | **20** | **35** |
| **Mechanical debridements per study participant** |  |  |  |  |
| Mean (SD) | 5.0 (5.3) | 9.3 (13.8) | 8.5 (8.8) | 10.0 (13.9) |
| Min – Max | 1 - 23 | 1 - 70 | 1 - 26 | 1 - 77 |
| **Time expenditure per study participant, minutes** |  |  |  |  |
| Mean (SD)  Min – Max | 11.6 (9.8)  2 – 30 | 7.3 (3.7)  2 – 30 | 10.8 (8.3)  1 – 30 | 7.9 (5.0)  1 – 30 |
| **Human Resources involved**, No. (M**ean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary N | 4 (13.0) | 3 (7.3) | 6 (5.0) | 0 (0) |
| Nursing staff N | 69 (12.6) | 227 (7.4) | 153 (10.2) | 200 (9.8) |
| Assistant physician (resident) N | 22 (6.8) | 77 (7.9) | 23 (8.1) | 46 (6.7) |
| Specialist physician (consultant) N | 34 (16.7) | 61 (8.1) | 18 (11.2) | 58 (10.7) |
| **Study participants with application of wound drainage,** No. | **30** | **17** | **3** | **2** |
| **Wound drainage applications per study participant** |  |  |  |  |
| Mean (SD) | 1.8 (1.9) | 3.4 (4.2) | 1.7 (0.6) | 14 (17) |
| Min – Max | 1 - 10 | 1 - 18 | 1 - 2 | 2 - 26 |
| **Time expenditure per study participant, minutes** |  |  |  |  |
| Mean (SD)  Min – Max | 10.9 (15.7)  1 – 75 | 19.3 (29.1)  1 – 160 | 12.0 (3.6)  8 – 15 | 12.6 (2.5)  10 – 15 |
| **Human Resources involved**, No. (M**ean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary | 4 (6.8) | 1 (15.0) | 1 (15.0) | 0 (0) |
| Nursing staff | 45 (11.2) | 54 (15.9) | 3 (8.7) | 28 (12.9) |
| Assistant physician (resident) | 30 (8.9) | 23 (26.5) | 1 (15.0) | 2 (10.0) |
| Specialist physician (consultant) | 37 (11.4) | 22 (32.4) | 2 (12.5) | 0 (0) |
| **Study participants with other inpatient procedures,** No. | **160** | **118** | **96** | **94** |
| **Inpatient other procedures per study participant** |  |  |  |  |
| Mean (SD) | 4.6 (7.3) | 7.4 (9.0) | 6.1 (6.3) | 8.4 (10.0) |
| Min – Max | 1 - 76 | 1 - 43 | 1 - 32 | 1 - 52 |
| **Time expenditure per study participant, minutes** |  |  |  |  |
| Mean (SD)  Min – Max | 13.1 (11.9)  1 – 105 | 10.1 (11.0)  1 – 100 | 8.3 (5.8)  1 – 37 | 7.9 (7.6)  1 – 60 |
| **Human Resources involved**, No. (M**ean time per study participant** in minutes) |  |  |  |  |
| Nursing auxiliary | 26 (27.1) | 44 (12.6) | 19 (8.7) | 28 (8.1) |
| Nursing staff | 515 (11.8) | 735 (8.0) | 354 (8.6) | 475 (7.7) |
| Assistant physician (resident) | 313 (16.0) | 213 (12.0) | 89 (9.8) | 135 (12.5) |
| Specialist physician (consultant) | 191 (17.4) | 184 (11.7) | 115 (8.6) | 122 (6.4) |

**eTable 26: Wound-related procedures performed during the inpatient and outpatient post-NPWT CWT period in the ITT population (NPWT arm only)**

|  |  |  |
| --- | --- | --- |
| **Treatment sectors** | **Inpatient** | **Outpatient** |
| **Study participants with wound cleansing,** No. | 43 | 69 |
| **Inpatient wound cleansings per study participant** | 333 | 543 |
| Mean (SD) per patient | 7.7 (8.5) | 7.9 (6.7) |
| Min – Max | 1 - 43 | 1 - 36 |
| **Time expenditure per study participant,** minutes  Mean (SD)  Min – Max | 6.3 (7.9)  1 – 70 | 5.9 (4.9)  1 – 39 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |
| Nursing auxiliary | 14 (8.4) | 8 (4.5) |
| Nursing staff | 206 (6.8) | 406 (1.7) |
| Assistant physician (resident) | 165 (9.9) | 122 (6.5) |
| Specialist physician (consultant) | 34 (7.8) | 40 (4.9) |
| **Study participants with wound lavage,** No. | 20 | 31 |
| **Inpatient wound lavages per study participant** | 123 | 191 |
| Mean (SD) | 6.2 (4.5) | 6.1 (7.1) |
| Min – Max | 1 - 14 | 1 - 30 |
| **Time expenditure per study participant, minutes**  Mean (SD)  Min – Max | 6.8 (6.8)  2 – 35 | 6.0 (5.5)  1 – 20 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |
| Nursing auxiliary | 3 (11.7) | 3 (5.3) |
| Nursing staff | 57 (8.1) | 103 (6.4) |
| Assistant physician (resident) | 77 (8.6) | 31 (6.6) |
| Specialist physician (consultant) | 20 (5.8) | 9 (3.9) |
| **Study participants with sharp debridement (using scalpel or curette at bedside),** No. | 5 | 8 |
| **Inpatient sharp debridements per study participant** | 8 | 11 |
| Mean (SD) | 1.6 (0.5) | 1.4 (1.1) |
| Min – Max | 1 - 2 | 1 - 4 |
| **Time expenditure per study participant, minutes**  Mean (SD)  Min – Max | 12.6 (9.2)  5 – 30 | 10.5 (12.9)  1 – 45 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |
| Nursing auxiliary | 0 (0) | 0 (0) |
| Nursing staff | 3 (16.7) | 3 (16.0) |
| Assistant physician (resident) | 6 (14.7) | 7 (15.0) |
| Specialist physician (consultant) | 3 (6.7) | 2 (3.5) |
| **Study participants with surgical debridement (in the operation theatre),** No. | 4 | 1 |
| **Inpatient surgical debridements per study participant** | 4 | 1 |
| Mean (SD) | 1 (NA) | 1 (NA) |
| Min – Max | 1 - 1 | 1 - 1 |
| **Time expenditure per study participant, minutes**  Mean (SD)  Min – Max | 19 (18.1)  3 - 45 | 15 (0)  15 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |
| Nursing auxiliary | 0 (0) | 0 (0) |
| Nursing staff | 3 (24.3) | 1 (15) |
| Assistant physician (resident) | 2 (30.0) | 1 (15.0) |
| Specialist physician (consultant) | 3 (20.3) | 0 (0) |
| **Study participants with autolytic debridement (Facilitation of the body`s own mechanisms of debridement with appropriate dressings),** No. | 3 | 4 |
| **Inpatient autolytic debridements per study participant** | 8 | 12 |
| Mean (SD) | 2.7 (2.1) | 3.0 (3.4) |
| Min – Max | 1 - 5 | 1 - 8 |
| **Time expenditure per study participant, minutes**  Mean (SD)  Min – Max | 8.0 (12.4)  1 – 30 | 7.3 (8.8)  2 – 30 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |
| Nursing auxiliary | 1 (30.0) | 4 (2.0) |
| Nursing staff | 8 (6.1) | 8 (9.9) |
| Assistant physician (resident) | 0 (0) | 0 (0) |
| Specialist physician (consultant) | 1 (30.0) | 1 (30.0) |
| **Study participants with biological debridement (larval (maggot) therapy),** No. | 0 | 0 |
| **Study participants with enzymatic debridement** | 0 | 1 |
| **Inpatient enzymatic debridements per study participant** | 0 | 5 |
| Mean (SD) | NA | 5 (NA) |
| Min – Max | NA | 5 - 5 |
| **Time expenditure per study participant,** minutes  Mean (SD)  Min – Max | NA | 8 (NA)  8 - 8 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |
| Nursing auxiliary | NA | 0 (0) |
| Nursing staff | NA | 5 (8.0) |
| Assistant physician (resident) | NA | 0 (0) |
| Specialist physician (consultant) | NA | 0 (0) |
| **Study participants with Mechanical debridement (wet-to-dry dressings),** No. | 7 | 13 |
| **Inpatient mechanical debridements per study participant** | 53 | 86 |
| Mean (SD) | 7.6 (7.2) | 6.6 (6.7) |
| Min – Max | 1 - 22 | 1 - 22 |
| **Time expenditure per study participant, minutes**  Mean (SD)  Min – Max | 5.3 (2.0)  3 – 10 | 7.6 (4.1)  1 – 20 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |
| Nursing auxiliary | 1 (7.0) | 0 (0) |
| Nursing staff | 39 (5.2) | 79 (7.7) |
| Assistant physician (resident) | 14 (5.5) | 18 (7.6) |
| Specialist physician (consultant) | 6 (8.0) | 5 (6.4) |
| **Study participants with application of wound drainage,** No. | 1 | 0 |
| **Inpatient wound drainage applications per study participant** | 1 | 0 |
| Mean (SD) | 1 (NA) | NA |
| Min – Max | 1 - 1 | NA |
| **Time expenditure per study participant, minutes**  Mean (SD)  Min – Max | 3 (-)  3 – 3 | NA |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |
| Nursing auxiliary | 0 (0) | NA |
| Nursing staff | 1 (3.0) | NA |
| Assistant physician (resident) | 1 (3.0) | NA |
| Specialist physician (consultant) | 1 (3.0) | NA |
| **Study participants with other wound-related procedures,** No. | 28 | 40 |
| **Inpatient other procedures per study participant** | 196 | 220 |
| Mean (SD) | 7.0 (13.6) | 5.5 (6.1) |
| Min – Max | 1 - 71 | 1 - 26 |
| **Time expenditure per study participant, minutes**  Mean (SD)  Min – Max | 8.0 (12.6)  1 – 105 | 6.8 (4.1)  1 – 20 |
| **Human Resources involved**, No. (**Mean time per study participant** in minutes) |  |  |
| Nursing auxiliary | 6 (45.8) | 8 (8.9) |
| Nursing staff | 163 (6.3) | 153 (8.0) |
| Assistant physician (resident) | 45 (13.4) | 24 (8.0) |
| Specialist physician (consultant) | 8 (36.6) | 23 (6.5) |

**eTable 27: Wound closure documentation in the ITT population**

|  |  |  |  |
| --- | --- | --- | --- |
| **Randomized treatment arms / Statistical significance** | **NPWT** | **SCWT** | **p-Valie**  **(test used)** |
| **Study participants in the ITT population,** No. | **256** | **251** | **NA** |
| Study participants with early study termination before day 42 and without wound closure, No. | 18 | 15 | NA |
| **Study participants with complete, sustained and verified wound closure during the study treatment time of 42 days, No. (%)** | **92 (35.9%)** | **54 (21.5%)** | **.003**  **(Chi2 test)** |
| Study participants with closed wound which violated at least one of the criteria for complete, sustained, and verified wound closure, No. | 41 | 29 | NA |
| **∑ Study participants with closed wound documented within 42 days, No. (%)** | **133 (52.0%)** | **83 (33.1%)** | NA |
| Study participants with wound closure documented during follow up with a date, No. | 56 | 85 | NA |
| Study participants with wound closure documented during follow up without a date+\*, No. | 11 | 21 | NA |
| Study participants with wound closure during follow up at a date later than 135 days (with date set to 135 days), No. | 1 | 0 | NA |
| Study participants with wound closure visit and/or wound closure confirmation visit during follow up, No. | 3 | 6 | NA |
| **∑ Study participants with wound closure documented during follow up, No. (%)** | **71 (27.7%)** | **112 (44.6%)** | **NA** |
| **Study participants with wound closure during the overall study observation period of 132 days** | **204 of 256 (79.7%)** | **195 of 251 (77.7%)** | **.583**  **(Chi2 test)** |
| **Time until wound closure during the overall study observation period of 132 days Median (SE)** | **41 (2.4)** | **62 (4.5)** | **.001**  **(Log-rank test)** |

+For one study participant, wound closure was documented during the follow up visit after 87 days (August 18, 2015) but without giving a concrete date only indicating July. During the study visit at end of maximum treatment time after 42 days, the wound was documented to be still open. For this study participant wound closure was assumed at July 15, 2015.

\*For study participants with wound closure documented during follow up but without indicating a date, the median of all wound closures that occurred during the follow up period (day 71) was assumed and used for further analyses.

**eTable 28: Period of working disability in the ITT population**

|  |  |  |  |
| --- | --- | --- | --- |
| **Randomized treatment arms / Statistical significance** | **NPWT** | **CWT** | **p**  **(test)** |
| **Study participants in the ITT population,** No. | 256 | 251 | NA |
| **Study participants with employment status available at the end of the active study treatment period,** No. | 165 of 256 | 164 of 251 | NA |
| **Study participants gainfully employed,** No. | 41 of 165 | 48 of 164 | NA |
| **Period of disability for study participants gainfully employed** |  |  |  |
| Study participants with data available, No. | 32 | 37 |  |
| Mean (SD | 41.1 (5.0) | 39.0 (9.8) | .452  (Mann-Whitney U) |
| Min - Max | 25 – 45 | 4 – 45 |

**eTable 29: Mobility and leisure activities during the active study treatment time of 42 days in the ITT population**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Randomized treatment arms** | **NPWT** | | **CWT** | |
| **Study participants in the ITT population,** No. | **256** | | **251** | |
| **Survey date** | **Baseline** | **End of active study treatment time after 42 days or at wound closure confirmation** | **Baseline** | **End of active study treatment time after 42 days or at wound closure confirmation** |
| **Mobility\*** |  |  |  |  |
| Study participants with information available N | 256 | 162 | 251 | 159 |
| Bedridden or mobilized in a wheel chair | 12 | 12 | 13 | 11 |
| Able to move freely within home | 30 | 14 | 29 | 13 |
| Able to leave home | 214 | 137 | 211 | 133 |
| **Leisure activities\*** |  |  |  |  |
| Study participants with information available N | 254 | 156 | 247 | 157 |
| Indoor activities | 61 | 49 | 63 | 49 |
| Outdoor activities | 172 | 99 | 142 | 102 |
| Recreational sports | 43 | 12 | 63 | 14 |
| Competitive sports | 2 | 1 | 2 | 0 |

\*Multiple answers possible