**Supplementary file 5**

**Table SF5: Secondary outcome measures, including a per protocol population analysis (LARS score, FIQL, EORTC QLQ-CR29).**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Measurement nr.** | **Intention to treat** | | | | **Per protocol** | | |
| **Control group**  **n=51** | **PFR group  n=44** | | **p value** | **Control group**  **n=49** | **PFR group  n=36** | **p value** |
| **Fecal Incontinence related Quality of Life (FIQL)** | | | | | | | | |
| Lifestyle | | | | | | | | |
| Total score, median (IQR) | M2 (baseline) | 2·80 (2·10) | 2·10 (1·68) | | - | 2·80 (2·05) | 2·00 (1·98) | - |
| M3 | 3·10 (2·60) | 3·05 (1·57) | | - | 3·10 (2·60) | 3·40 (1·55) | - |
| Change score (M3-M2) | Objected mean difference | 0·00  95% CI -0·49 to 0·49 | 0·41  95% CI -0·03 to 0·85 | | - | 0·00  95% CI -0·50 to 0·51 | 0·53  95% CI 0·05 to 1·01 | - |
| Adjusted mean difference \* | 0·04  95% CI -0·34 to 0·42 | 0·36  95% CI -0·05 to 0·77 | | 0·26 | 0·07  95% CI -0·32 to 0·46 | 0·44  95% CI -0·02 to 0·90 | 0·23 |
| Coping and behaviour | | | | | | | | |
| Total score, median (IQR) | M2 (baseline) | 2·22 (1·67) | 1·89 (1·08) | | - | 2·22 (1·72) | 1·78 (1·17) | - |
| M3 | 2·33 (2·11) | 2·44 (1·61) | | - | 2·33 (2·11) | 2·56 (1·75) | - |
| Change score (M3-M2) | Objected mean difference | -0·11  95% CI -0·51 to 0·30 | 0·36  95% CI 0·01 to 0·72 | | - | -0·11  95% CI -0·53 to 0·32 | 0·53  95% CI 0·16 to 0·91 | - |
| Adjusted mean difference \* | 0·01  95% CI -0·29 to 0·31 | 0·23  95% CI -0·10 to 0·55 | | 0·34 | 0·03  95% CI -0·28 to 0·35 | 0·34  95% CI -0·02 to 0·71 | 0·21 |
| Depression and self-perception | | | | | | | | |
| Total score, median (IQR) | M2 (baseline) | 2·70 (1·48) | 3·03 (1·38) | | - | 2·70 (1·68) | 2·99 (1·58) | - |
| M3 | 2·54 (2·14) | 3·29 (1·13) | | - | 2·54 (2·30) | 3·42 (1·22) | - |
| Change score (M3-M2) | Objected mean difference | -0·07  95% CI -0·45 to 0·31 | 0·18  95% CI -0·18 to 0·53 | | - | -0·08  95% CI -0·47 to 0·31 | 0·27  95% CI -0·11 to 0·65 | - |
| Adjusted mean difference \* | -0·15  95% CI -0·45 to 0·14 | 0·28  95% CI-0·04 to 0·59 | | 0·05 | -0·15  95% CI -0·45 to 0·15 | 0·36  95% CI 0·02 to 0·71 | 0·03 |
| Embarrassment | | | | | | | | |
| Total score, median (IQR) | M2 (baseline) | 2·67 (2·33) | 3·00 (1·67) | | - | 2·67 (2·33) | 3·00 (1·67) |  |
| M3 | 2·33 (2·67) | 3·17 (1·92) | | - | 2·33 (3·00) | 3·17 (1·92) |  |
| Change score (M3-M2) | Objected mean difference | -0·23  95% CI -0·76 to 0·30 | 0·05  95% CI -0·43 to 0·52 | | - | -0·23  95% CI -0·78 to 0·33 | 0·17  95% CI -0·32 to 0·66 |  |
| Adjusted mean difference \* | -0·33  95% CI -0·72 to 0·06 | 0·16  95% CI -0·26 to 0·58 | | 0·09 | -0·30  95% CI -0·70 to 0·11 | 0·26  95% CI -0·21 to 0·73 | 0·08 |
| **LARS score** | | | | | | | | |
| Total LARS score, median (IQR) | M2 (baseline) | 31·0 (14·0) | 36·0 (8·0) | | - | 29·0 (13·0) | 36·0 (9·0) | - |
| M3 | 31·0 (16·0) | 31·0 (9·0) | | - | 29·0 (16·0) | 31·0 (9·0) | - |
| Change score (M3-M2) | Objected mean difference | -1·3  95% CI -3·5 to 1·0 | -3·6  95% CI -5·9 to -1·4 | | - | -1·3  95% CI -3·6 to 1·0 | -4·3  95% CI -6·9 to -1·8 | - |
| Adjusted mean difference \* | -2·3  95% CI -4·3 to -0·3 | -2·4  95% CI -4·5 to -3·1 | | 0·93 | -2·3  95% CI -4·4 to -0·3 | -2·9  95% CI -5·3 to -0·4 | 0·75 |
| **LARS categories, n (%)** | | | | | | | | |
| No LARS  Minor LARS  Major LARS | M2 (baseline) | 11 (21·6)  14 (27·5)  26 (51·0) | 4 (9·1)  5 (11·4)  35 (79·5) | | 0·02 | 11 (22·4)  14 (28·6)  24 (49·0) | 3 (8·3)  4 (11·1)  28 (80·6) | 0·01 |
| No/minor vs. major LARS | M2 (baseline) | - | - | | <0·01 |  |  | <0·01 |
| No LARS  Minor LARS  Major LARS | M3 | 18 (35·3)  7 (13·7)  26 (51·0) | 7 (15·9)  11 (25·0) 26 (59·1) | | 0·07 | 18 (36·7)  7 (14·3)  24 (49·0) | 6 (16·7)  9 (25·0)  21 (58·3) | 0·10 |
| No/minor vs. major LARS | M3 | - | - | | 0·43 | - | - | 0·39 |
| **EORTC QLQ-CR29** | | **n=50** | | **n=44** | **-** | **n=49** | **n=36** | **-** |
| Body image | M2 (baseline) | 14·0 (19·29) | 11·4 (14·7) | | - | 12·7 (18·6) | 11·4 (15·1) | - |
| M3 | 14·2 (22·9) | 9·3 (13·3) | | - | 12·9 (22·6) | 9·3 (11·7) | - |
| Objected mean difference | 0·2  95% CI -4·3 to 4·7 | -2·0  95% CI -5·4 to 1·3 | | - | 0·5  95% CI -4·2 to 5·1 | -2·2  95% CI -5·8 to 1·5 | - |
| Adjusted mean difference \* | 0·5  95% CI -3·3 to 4·2 | -2·3  95% CI -6·3 to 1·7 | | 0·32 | 0·6  -3·3 to 4·5 | -2·3  95% CI -6·8 to 2·2 | 0·33 |
| Anxiety | M2 (baseline) | 26·7 (23·3) | 17·4 (22·1) | | - | 25·7 (23·1) | 19·4 (23·1) |  |
| M3 | 24·7 (29·2) | 12·9 (16·4) | | - | 23·8 (29·7) | 13·0 (16·5) |  |
| Objected mean difference | -2·0  95% CI -9·3 to 5·3 | -4·6  95% CI -10·6 to 1·5 | | - | -1·4  95% CI -8·8 to 6·1 | -6·5  -13·5 to 0·6 |  |
| Adjusted mean difference \* | 0·0  95% CI -5·9 to 5·8 | -6·8  95% CI -13·1 to -0·5 | | 0·13 | -0·2  95% CI -6·4 to 6·0 | -8·1  95% CI -15·3 to -0·9 | 0·11 |
| Weight | M2 (baseline) | 8·7 (16·2) | 13·6 (23·1) | | - | 7·6 (15·7) | 13·0 (22·9) | - |
| M3 | 16·0 (22·6) | 12·9 (23·0) | | - | 15·0 (22·6) | 13·0 (22·9) | - |
| Objected mean difference | 7·3  95% CI 0·6 to 14·0 | -0·8  95% CI -6·7 to 5·2 | | - | 7·6  95% CI 0·7 to 14·6 | 0·0  95% CI -5·4 to 5·4 | - |
| Adjusted mean difference \* | 6·3  95% CI 0·6 to 12·0 | 0·4  95% CI -5·6 to 6·5 | | 0·17 | 6·8  95% CI 1·1 to 12·4 | 1·2  95% CI -5·4 to 7·8 | 0·21 |
| Urinary Frequency | M2 (baseline) | 37·3 (29·8) | 40·9 (29·5) | | - | 37·5 (30·5) | 40·7 (28·9) | - |
| M3 | 34·0 (34·0) | 30·3 (32·0) | | - | 33·3 (34·0) | 28·7 (32·0) | - |
| Objected mean difference | -3·3  95% CI -12·4 to 5·7 | -10·6  95% CI -20·3 to -0·9 | | - | -4·2  95% CI -13·5 to 5·1 | -12·0  95% CI -23·5 to -0·6 | - |
| Adjusted mean difference \* | -4·1  95% CI-12·3 to 4·1 | -9·7  95% CI -18·4 to -1·1 | | 0·35 | -4·8  95% CI -13·4 to 3·7 | -11·2  95% CI -21·0 to -1·3 | 0·34 |
| Blood and Mucus in Stool | M2 (baseline) | 5·7 (11·0) | 8·3 (11·1) | | - | 5·6 (11·1) | 6·9 (8·3) | - |
| M3 | 4·7 (8·9) | 5·3 (11·8) | | - | 4·8 (9·0) | 4·6 (10·2) | - |
| Objected mean difference | -1·0  95% CI -3·8 to 1·8 | -3·0  95% CI -6·7 to 0·6 | | - | -0·7  95% CI -3·5 to 2·1 | -2·3  95% CI -6·2 to 1·5 | - |
| Adjusted mean difference \* | -1·7  95% CI -4·3 to 0·9 | -2·3  95% CI -5·0 to 0·5 | | 0·76 | -1·0  95% CI -3·6 to 1·5 | -1·9  95% CI -4·7 to 1·0 | 0·55 |
| Stool frequency | M2 (baseline) | 35·3 (19·8) | 40·2 (20·7) | | - | 34·7 (19·7) | 36·6 (20·2) | - |
| M3 | 27·0 (23·1) | 31·1 (20·2) | | - | 25·2 (22·1) | 27·8 (17·4) | - |
| Objected mean difference | -8·3  95% CI -15·0 to -1·7 | -9·1  95% CI -16·3 to -1·9 | | - | -9·0  95% CI -15·4 to -2·6 | -8·8  95% CI -16·1 to -1·5 | - |
| Adjusted mean difference \* | -9·7  95% CI -15·4 to -4·0 | -7·6  95% CI -13·7 to -1·5 | | 0·62 | -9·5  95% CI -14·8 to -4·2 | -8·2  95% CI -14·3 to -2·0 | 0·75 |
| Urinary incontinence | M2 (baseline) | 6·7 (15·1) | 9·9 (17·0) | | - | 6·9 (15·3) | 9·3 (15·1) | - |
| M3 | 7·3 (14·5) | 6·8 (13·6) | | - | 7·5 (15·6) | 7·4 (14·1) | - |
| Objected mean difference | 0·7  95% CI -3·4 to 4·7 | -3·0  95% CI -7·3 to 1·2 | | - | 0·0  95% CI -4·0 to 4·0 | -1·9  95% CI -6·5 to 2·8 | - |
| Adjusted mean difference \* | 0·0  95% CI -3·4 to 3·4 | -2·2  95% CI -5·8 to 1·4 | | 0·38 | -0·4  95% CI -3·9 to 3·1 | -1·3  95% CI -5·3 to 2·7 | 0·75 |
| Dysuria | M2 (baseline) | 2·0 (10·5) | 4·6 (11·6) | | - | 2·1 (10·7) | 4·6 (11·7) | - |
| M3 | 1·3 (6·6) | 0·8 (5·0) | | - | 1·4 (6·7) | 0·0 (0·0) | - |
| Objected mean difference | 0·7  95% CI -2·0 to 0·7 | -3·8  95% CI -7·0 to -0·5 | | - | -0·7  95% CI -2·1 to 0·7 | -4·6  95% CI -8·6 to -0·7 | - |
| Adjusted mean difference \* | -1·4  95% CI -2·6 to -0·2 | -2·9  95% CI -4·2 to -1·7 | | 0·09 | -1·4  95% CI -2·5 to -0·4 | -3·6  95% CI -4·9 to -2·4 | 0·01 |
| Abdominal Pain | M2 (baseline) | 14·7 (21·5) | 14·4 (25·3) | | - | 14·6 (21·6) | 16·7 (27·0) | - |
| M3 | 9·3 (19·1) | 13·6 (25·2) | | - | 9·5 (19·2) | 11·1 (21·1) | - |
| Objected mean difference | -5·3  95% CI -11·5 to 0·8 | -0·8  95% CI -0·4 to 7·8 | | - | -4·9  95% CI -11·2 to 1·5 | -5·6  95% CI -12·9 to 1·8 | - |
| Adjusted mean difference \* | -5·3  95% CI -11·0 to -0·5 | -0·9  95% CI -7·0 to 5·3 | | 0·30 | -5·4  95% CI -10·3 to -0·4 | -4·9  95% CI -10·6 to 0·8 | 0·90 |
| Buttock Pain | M2 (baseline) | 24·0 (29·4) | 23·5 (31·8) | | - | 22·2 (27·8) | 23·1 (32·7) | - |
| M3 | 15·3 (22·5) | 12·1 (25·0) | | - | 15·0 (22·6) | 11·1 (22·5) | - |
| Objected mean difference | -8·7  95% CI -16·3 to -1·1 | -11·4  95% CI -20·1 to -2·6 | | - | -6·9  95% CI -14·4 to 0·5 | -12·0  95% CI -21·8 to -2·3 | - |
| Adjusted mean difference \* | -8·5  95% CI -14·3 to -2·7 | -11·5  95% CI -17·7 to -5·4 | | 0·48 | -7·2  95% CI -12·9 to -1·5 | -11·7  95% CI -18·3 to -5·2 | 0·30 |
| Bloating | M2 (baseline) | 16·0 (23·6) | 17·4 (23·3) | | - | 15·3 (23·8) | 16·7 (23·2) | - |
| M3 | 18·0 (22·5) | 15·9 (22·1) | | - | 16·3 (21·6) | 13·0 (16·5) | - |
| Objected mean difference | 2·0  95% CI -5·8 to 9·8 | -1·5  95% CI -9·1 to 6·0 | | - | 1·4 95% CI -6·6 to 9·4 | -3·7  95% CI -11·2 to 3·8 | - |
| Adjusted mean difference \* | 1·6  95% CI -4·4 to 7·5 | -1·0  95% CI -7·3 to 5·3 | | 0·56 | 1·0  95% CI -4·4 to 6·3 | -3·1  95% CI -9·3 to 3·1 | 0·33 |
| Dry Mouth | M2 (baseline) | 12·0 (17·5) | 15·2 (20·9) | | - | 11·1 (17·3) | 12·0 (16·2) | - |
| M3 | 17·3 (24·5) | 15·2 (23·2) | | - | 17·7 (24·6) | 13·9 (21·6) | - |
| Objected mean difference | 5·3  95% CI 0·1 to 10·5 | 0·0  95% CI –6·6 to 6·6 | | - | 6·3  95% CI 1·1 to 11·4 | 1·9  95% CI -5·7 to 9·5 | - |
| Adjusted mean difference \* | 5·0  95% CI -0·5 to 10·4 | 0·4  95% CI -5·4 to 6·2 | | 0·26 | 6·2  95% CI 0·5 to 11·8 | 2·0  95% CI -4·6 to 8·5 | 0·34 |
| Hair Loss | M2 (baseline) | 2·0 (10·5) | 1·5 (10·1) | | - | 2·1 (10·7) | 1·9 (11·1) | - |
| M3 | 0·7 (4·7) | 1·5 (7·0) | | - | 0·7 (4·8) | 1·9 (7·7) | - |
| Objected mean difference | -1·3  95% CI -4·6 to 2·0 | 0·0  95% CI -3·8 to 3·8 | | - | -1·4  95% CI -4·8 to 2·0 | 0·0  95% CI -4·7 to 4·7 | - |
| Adjusted mean difference \* | -1·1  95% CI -2·8 to 0·6 | -0·3  95% CI -2·0 to 1·5 | | 0·50 | -1·3  95% CI -3·1 to 0·5 | -1·1  95% CI -2·2 to 1·9 | 0·41 |
| Taste | M2 (baseline) | 1·3 (6·6) | 6·1 (14·9) | | - | 0·7 (4·8) | 6·5 (15·6) | - |
| M3 | 0·0 (0·0) | 2·3 (8·5) | | - | 0·0 (0·0) | 1·9 (7·7) | - |
| Objected mean difference | -1·3  95% CI -3·2 to 0·5 | -3·8  95% CI -8·3 to 0·7 | | - | -0·7  95% CI -2·1 to 0·7 | -4·6  95% CI -9·4 to 0·2 | - |
| Adjusted mean difference \* | -3·2  95% CI -4·8 to -1·6 | -1·6  95% CI -3·3 to 0·1 | | 0·18 | -2·7  95% CI -4·1 to -1·4 | -1·9  95% CI -3·5 to -0·4 | 0·47 |
| Flatulence | M2 (baseline) | 40·0 (23·3) | 40·9 (25·8) | | - | 39·6 (23·5) | 39·8 (23·7) | - |
| M3 | 37·3 (27·5) | 34·9 (24·9) | | - | 35·4 (27·6) | 33·3 (26·4) | - |
| Objected mean difference | -2·7  95% CI -9·5 to 4·2 | -6·1  95% CI -14·3 to 2·2 | | - | -3·5  95% CI -10·5 to 3·5 | -6·5  95% CI -15·8 to 2·8 | - |
| Adjusted mean difference \* | -2·9  95% CI -9·3 to 3·6 | -5·8  95% CI -12·7 to 1·1 | | 0·53 | -3·5  95% CI -10·3 to 3·3 | -6·4  95% CI -14·2 to 1·4 | 0·58 |
| Faecal incontinence | M2 (baseline) | 19·3 (30·2) | 18·2 (22·1) | | - | 18·1 (29·9) | 18·5 (21·7) | - |
| M3 | 14·7 (22·5) | 16·7 (26·4) | | - | 13·6 (22·5) | 15·7 (24·5) | - |
| Objected mean difference | -4·7  95% CI -10·4 to 1·1 | -1·5  95% CI -10·8 to 7·7 | | - | -4·2  95% CI -10·0 to 1·7 | -2·7  95% CI -12·6 to 7·1 | - |
| Adjusted mean difference \* | -4·4  95% CI -10·3 to 1·6 | -1·9  95% CI -8·2 to 4·5 | | 0·57 | -4·3  95% CI -10·0 to 1·5 | -2·6  95% CI -9·3 to 4·0 | 0·71 |
| Sore Skin | M2 (baseline) | 6·7 (24·5) | 23·5 (31·0) | | - | 16·0 (24·8) | 19·4 (28·0) | - |
| M3 | 10·7 (19·6) | 14·4 (23·2) | | - | 9·5 (19·2) | 13·0 (20·0) | - |
| Objected mean difference | -6·0  95% CI -13·1 to 1·1 | -9·1  95% CI -17·7 to -0·5 | | - | -6·3  95% CI -13·6 to 1·1 | -6·5  95% CI -14·5 to 1·5 | - |
| Adjusted mean difference \* | -8·1  95% CI -13·5 to -2·7 | -7·0  95% CI -12·5 to -0·9 | | 0·73 | -7·2  95% CI -12·3 to -2·2 | -5·2  95% CI -11·0 to 0·7 | 0·60 |
| Embarrassment | M2 (baseline) | 24·7 (28·4) | 25·8 (26·8) | | - | 23·6 (28·3) | 24·1 (26·0) | - |
| M3 | 15·3 (22·5) | 15·2 (23·2) | | - | 14·3 (22·6) | 13·9 (21·6) | - |
| Objected mean difference | -9·3  95% CI -15·4 to -3·3 | -10·6  95% CI -18·7 to -2·5 | | - | -9·0  95% CI -15·3 to -2·8 | -10·2  95% CI -19·1 to -1·3 | - |
| Adjusted mean difference \* | -9·6  95% CI -14·9 to -4·3 | -10·3  95% CI -16·0 to -4·6 | | 0·86 | -9·1  95% CI -14·5 to -3·8 | -10·0  95% CI -16·2 to -3·9 | 0·83 |

\* ANCOVA with mean change in EORTC QLQ-CR29 domain score (M3-M2) adjusted for baseline score.   
Due to rounding, a difference in the mean scores and mean change scores may be possible.