

**Appendix 4. Trend Analysis of the Incidence of the Primary Outcome and Intervention Rates Over the Course of the Study, for the Whole Study Population**

|                    | 1st<br>semester<br>(n=1350) | 2nd<br>semester<br>(n=1633) | 3rd<br>semester<br>(n=1469) | 4th<br>semester<br>(n=1122) | 5th<br>semester<br>(n=1001) | 6th<br>semester<br>(n=1155) | p*               |
|--------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|------------------|
|                    | %                           | %                           | %                           | %                           | %                           | %                           |                  |
| Metabolic acidosis | 0.5                         | 0.5                         | 0.7                         | 0.3                         | 0.4                         | 0.6                         | 0.693            |
| IVD for NRFS       | 14                          | 13                          | 11                          | 11                          | 12                          | 10                          | <b>0.014</b>     |
| Cesarean for NRFS  | 7                           | 7                           | 7                           | 5                           | 5                           | 6                           | <b>0.036</b>     |
| IVD                | 32                          | 30                          | 28                          | 29                          | 35                          | 30                          | 0.976            |
| Cesarean           | 23                          | 22                          | 21                          | 20                          | 16                          | 19                          | <b>&lt;0.001</b> |

\*Cochran-Armitage test for trend

IVD = instrumental vaginal delivery; NRFS = non-reassuring fetal state

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|                                         | Experimental arm | Control arm     | Relative risk<br>(95% CI) |
|-----------------------------------------|------------------|-----------------|---------------------------|
| <b>2011/2012</b>                        | <b>(n=2182)</b>  | <b>(n=2030)</b> |                           |
| Metabolic acidosis <i>n</i> (%)         | 9 (0.412)        | 15 (0.739)      | 0.56 (0.24-1.27)          |
| Umbilical blood pH <7.10 <i>n</i> (%)   | 85 (3.9)         | 81 (4.0)        | 0.98 (0.72-1.31)          |
| Umbilical blood pH <7.15 <i>n</i> (%)   | 199 (9.1)        | 195 (9.6)       | 0.95 (0.79-1.14)          |
| 5-min Apgar <7 <i>n</i> (%)             | 26 (1.2)         | 33 (1.6)        | 0.73 (0.44-1.22)          |
| Perinatal death <i>n</i> (%)            | 1 (0.046)        | 0 (0.000)       | 2.79 (0.11-68.48)         |
| HIE of any grade <i>n</i> (%)           | 5 (0.229)        | 7 (0.345)       | 0.66 (0.21-2.09)          |
| Grade 2 or 3 HIE <i>n</i> (%)           | 4 (0.183)        | 1 (0.049)       | 3.72 (0.42-33.27)         |
| Cesarean delivery <i>n</i> (%)          | 461 (21.1)       | 462 (22.8)      | 0.94 (0.83-1.05)          |
| Cesarean delivery for NRFS <i>n</i> (%) | 148 (6.8)        | 144 (7.1)       | 0.96 (0.77-1.19)          |
| IVD <i>n</i> (%)                        | 691 (31.7)       | 591 (29.1)      | 1.09 (0.99-1.19)          |
| IVD for NRFS <i>n</i> (%)               | 281 (12.9)       | 241 (11.9)      | 1.08 (0.92-1.27)          |
| NICU admission <i>n</i> (%)             | 85 (3.9)         | 86 (4.2)        | 0.92 (0.68-1.23)          |
| <b>2013/2014</b>                        | <b>(n=1779)</b>  | <b>(n=1739)</b> |                           |
| Metabolic acidosis <i>n</i> (%)         | 7 (0.393)        | 7 (0.402)       | 0.98 (0.34-2.78)          |
| Umbilical blood pH <7.10 <i>n</i> (%)   | 67 (3.8)         | 77 (4.4)        | 0.85 (0.62-1.17)          |
| Umbilical blood pH <7.15 <i>n</i> (%)   | 168 (9.4)        | 177 (10.2)      | 0.93 (0.76-1.13)          |
| 5-min Apgar <7 <i>n</i> (%)             | 21 (1.2)         | 19 (1.1)        | 1.08 (0.58-2.00)          |
| Perinatal death <i>n</i> (%)            | 0 (0.000)        | 0 (0.000)       | 0.98 (0.02-49.24)         |
| HIE of any grade <i>n</i> (%)           | 2 (0.112)        | 1 (0.057)       | 1.95 (0.18-21.54)         |
| Grade 2 or 3 HIE <i>n</i> (%)           | 1 (0.056)        | 0 (0.000)       | 2.93 (0.12-71.94)         |
| Cesarean delivery <i>n</i> (%)          | 348 (19.6)       | 310 (17.8)      | 1.10 (0.95-1.26)          |
| Cesarean delivery for NRFS <i>n</i> (%) | 110 (6.2)        | 95 (5.5)        | 1.13 (0.87-1.4822)        |
| IVD <i>n</i> (%)                        | 561 (31.5)       | 521 (30.0)      | 1.05 (0.95-1.16)          |
| IVD for NRFS <i>n</i> (%)               | 202 (11.4)       | 190 (10.9)      | 1.04 (0.86-1.25)          |
| NICU admission <i>n</i> (%)             | 52 (2.9)         | 57 (3.3)        | 0.89 (0.62-1.29)          |

IVD = instrumental vaginal delivery; NRFS = non-reassuring fetal state; HIE = hypoxic-ischemic encephalopathy; NICU = neonatal intensive care unit

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**Table 4.** Comparison of the incidence of the primary outcome and intervention rates in the two study arms, during the first and second halves of the study.

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