

1 Appendix

2 Per-protocol population

3 Perinatal outcomes

	Induction of labour (n=611)	Expectant management (n=647)	Relative risk (95% CI)	p-value
Composite adverse perinatal outcome*	10 (1.6%)	19 (2.9%)	0.56 (0.26 to 1.19)	0.13†
with Apgar score 5' <4 instead of <7	3 (0.5%)	8 (1.2%)	0.40 (0.11 to 1.49)	0.23†
including arterial pH <7.05	19 (3.1%)	26 (4.0%)	0.40 (0.11 to 1.49)	0.15†
Stillbirth	1 (0.2%)	2 (0.3%)	0.53 (0.05 to 5.82)	1.00†
Neonatal death, post-partum	0 (0.0%)	0 (0.0%)	n/a	-
Apgar score 5 min. post-partum [‡]				
<7	7 (1.1%)	16 (2.5%)	0.46 (0.19 to 1.12)	0.08
<4	0 (0.0%)	1 (0.2%)	n/a	-
Admission neonate to				
intensive care (NICU)	2 (0.3%)	6 (0.9%)	0.35 (0.07 to 1.74)	0.51†
medium care	39 (6.4%)	48 (7.4%)	0.86 (0.57 to 1.29)	0.45
Meconium aspiration syndrome [‡]	0 (0.0%)	2 (0.2%)	n/a	-
Plexus brachialis injury	0 (0.0%)	0 (0.0%)	n/a	-
Intracranial haemorrhage	0 (0.0%)	0 (0.0%)	n/a	-
Umbilical cord pH (arterial)				
pH <7.05	11 (1.8%)	10 (1.6%)	1.12 (0.49 to 2.58)	0.79
missing	366 (59.9%)	447 (69.6%)	n/c	-
Congenital abnormality	11 (1.8%)	12 (1.9%)	0.97 (0.42 to 2.18)	0.94
Hypoglycaemia [§]	1 (0.2%)	5 (0.8%)	0.21 (0.02 to 1.81)	0.22†
Neonatal infection / sepsis	23 (3.8%)	29 (4.5%)	0.84 (0.49 to 1.44)	0.52
Sex, female	305 (49.9%)	337 (52.1%)	0.96 (0.86 to 1.07)	0.44
Birth weight (g; mean, sd)	3,697 (414.4)	3,747 (433.5)	-50.2 (-97.2 to -3.2)**	0.04
Small of gestational age				
<2.3 rd percentile	11 (1.8%)	8 (1.2%)	1.46 (0.59 to 3.60)	0.42
<10 th percentile	40 (6.6%)	46 (7.1%)	0.92 (0.61 to 1.39)	0.69
Large for gestational age				
>90 th percentile	54 (8.8%)	74 (11.4%)	0.77 (0.55 to 1.08)	0.13
>97.7 th percentile	12 (2.0%)	22 (3.4%)	0.58 (0.29 to 1.16)	0.12

4 **Perinatal outcomes (per-protocol).** Data are n (%) or mean (standard deviation). Confidence intervals are 95%.

5 NICU: Neonatal Intensive Care Unit * Composite outcome defined as: perinatal mortality, and/or a 5-minute

6 Apgar-score below 7, and/or meconium aspiration syndrome, and/or plexus brachialis injury, and/or

7 intracranial haemorrhage, and/or NICU admission. [‡] Apgar score of the live births. [†] Fisher's exact test. [‡]

8 Defined as respiratory distress after birth in presence of meconium stained amniotic fluid). [§] Defined as

9 glucose concentration <1.9 mmol/L and need for intravenous glucose. [¶] Defined as clinical suspected findings,

10 or proved positive culture. ** Mean difference between groups with 95% confidence interval.

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12 Delivery outcomes

	Induction of labour (n=611)	Expectant management (n=647)	Relative risk (95% CI)	p-value
Gestational age at delivery (days; median, IQR)	288 (287 - 288)	290 (288 - 292)	-2.3 (-2.5 to -2.1)*	<0.001 †
Time randomisation to delivery (days; mean, sd)	2.2 (1.5)	4.5 (2.9)	-2.2 (-2.5 to -2.0)*	<0.001 †
Level of care at onset of labour				
Primary care	96 (15.7%)	474 (73.3%)	n/c	-
Secondary care	515 (84.3%)	173 (26.7%)	n/c	-
Onset of labour				
Spontaneous (reference)	92 (15.1%)	524 (81.0%)	1.00	-
Induction	519 (84.9%)	123 (19.0%)	4.47 (3.80 to 5.26)	<0.001
Mode of induction				
cervical ripening (catheter /prostaglandins)	304 / 519 (58.6%)	71 / 123 (57.7%)	1.01 (0.86 to 1.20)	0.86
amniotomy, without oxytocin	72 / 519 (13.9%)	12 / 123 (9.8%)	1.42 (0.80 to 2.54)	0.23
amniotomy, with oxytocin	135 / 519 (26.0%)	33 / 123 (26.8%)	0.97 (0.70 to 1.34)	0.85
Indication for induction				
randomisation	519 / 519 (100%)	0 / 123 (0.0%)	n/c	-
post-term pregnancy	0 / 519 (0.0%)	62 / 123 (50.4%)	n/c	-
fetal condition	0 / 519 (0.0%)	35 / 123 (28.5%)	n/c	-
maternal condition	0 / 519 (0.0%)	22 / 123 (17.9%)	n/c	-
elective / maternal wish	0 / 519 (0.0%)	0 / 123 (0.0%)	n/c	-
>24 h of ruptured membranes	0 / 519 (0.0%)	4 / 123 (3.3%)	n/c	-
other	0 / 519 (0.0%)	0 / 123 (0.0%)	n/c	-
Use of oxytocin	402 (65.8%)	255 (39.4%)	1.69 (1.49 to 1.87)	<0.001
Use of tocolytics	20 (3.3%)	13 (2.0%)	1.63 (0.82 to 3.25)	0.17
Maternal intrapartum infection				
fever during labour (≥38 °C)	33 (5.4%)	35 (5.4%)	0.99 (0.63 to 1.59)	0.99
use of antibiotics	34 (5.6%)	22 (3.4%)	1.64 (0.97 to 2.77)	0.07
Meconium stained amniotic fluid	82 (13.4%)	163 (25.2%)	0.53 (0.42 to 0.68)	0.001
Level of care at time of birth				
Primary care	44 (7.2%)	221 (34.2%)	n/c	-
Secondary care	567 (92.8%)	426 (65.8%)	n/c	-
Mode of delivery				
spontaneous vaginal delivery	484 (79.2%)	493 (76.2%)	1.04 (0.98 to 1.10)	0.20
operative vaginal delivery	56 (9.2%)	80 (12.4%)	0.74 (0.54 to 1.02)	0.07
(secondary) caesarean section	71 (11.6%)	74 (11.4%)	1.02 (0.75 to 1.38)	0.92
Indication successful operative vaginal delivery				
failure to progress at second stage	27 / 56 (48.2%)	37 / 80 (46.3%)	1.04 (0.73 to 1.49)	0.82
suspected fetal distress	24 / 56 (42.9%)	29 / 80 (36.3%)	1.18 (0.78 to 1.80)	0.43
suspected fetal distress and failure to progress	5 / 56 (8.9%)	14 / 80 (17.5%)	0.51 (0.19 to 1.34)	0.21‡
maternal complication or other	0 / 56 (0.0%)	0 / 80 (0.0%)	n/a	-
Indication secondary caesarean section				
failure to progress at first stage	27 / 71 (38.0%)	16 / 74 (21.6%)	1.76 (1.04 to 2.98)	0.04
failure to progress at second stage	8 / 71 (11.3%)	12 / 74 (16.2%)	0.69 (0.30 to 1.60)	0.39
failed OVD	3 / 71 (4.2%)	9 / 74 (12.2%)	0.35 (0.10 to 1.23)	0.13‡
suspected fetal distress	14 / 71 (19.7%)	18 / 74 (24.3%)	0.81 (0.44 to 1.50)	0.51
suspected fetal distress and failure to progress at first stage	3 / 71 (4.2%)	7 / 74 (9.5%)	0.45 (0.12 to 1.66)	0.33‡

suspected fetal distress and failure to progress at second stage	3 / 71 (4.2%)	3 / 74 (4.1%)	0.96 (0.22 to 4.99)	1.00†
maternal complication or other	13 / 71 (18.3%)	9 / 74 (12.2%)	1.51 (0.69 to 3.30)	0.31

13 **Delivery outcomes (per-protocol).** Data are n (%), mean and standard deviation, or median (IQR). OVD:
14 Operative Vaginal Delivery. * Mean difference between groups with 95% confidence interval. †Mann-Whitney
15 U test. ‡Fisher's exact test.

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18 **(Adverse) maternal outcomes**

	Induction of labour (n=611)	Expectant management (n=647)	Relative risk (95% CI)	p-value
Composite adverse maternal outcome*	84 (13.7%)	75 (11.6%)	1.19 (0.89 to 1.59)	0.25
Maternal death	0 (0.0%)	0 (0.0%)	n/a	-
Post-partum blood loss				
< 1000 mL (reference)	552 (90.3%)	592 (91.5%)	1.00	-
≥ 1000 mL	59 (9.7%)	55 (8.5%)	1.14 (0.80 to 1.61)	0.48
1000-1500 mL	23 (3.8%)	27 (4.2%)	0.92 (0.53 to 1.58)	0.76
>1500-2000 mL	15 (2.5%)	10 (1.6%)	1.59 (0.72 to 3.52)	0.25
> 2000 mL	21 (3.4%)	18 (2.8%)	1.24 (0.67 to 2.31)	0.49
Post-partum blood loss (mL; median, IQR)	300 (200 – 500)	300 (250 – 500)	-	0.18†
Transfusion (packed cells or plasma)	18 (2.9%)	13 (2.0%)	1.47 (0.72 to 2.97)	0.29
Manual removal placenta	29 (5.4%)	26 (4.5%)	1.18 (0.71 to 1.98)	0.52
Perineal tear				
episiotomy (without tear)	150 / 540 (27.8%)	181 / 573 (31.6%)	0.88 (0.73 to 1.05)	0.17
OASIS	16 / 540 (3.0%)	21 / 573 (3.7%)	0.81 (0.43 to 1.53)	0.51
third degree tear	10 / 540 (1.9%)	14 / 573 (2.4%)	0.79 (0.40 to 1.55)	0.49
fourth degree tear	5 / 540 (0.9%)	5 / 573 (0.9%)	1.06 (0.31 to 3.64)	1.00‡
episiotomy and third degree tear	0 / 540 (0.0%)	1 / 573 (0.2%)	-	-
episiotomy and fourth degree tear	1 / 540 (0.2%)	1 / 573 (0.2%)	1.06 (0.07 to 16.92)	1.00‡
Maternal admission (highest level of care)				
intensive care	3 (0.5%)	2 (0.3%)	1.59 (0.27 to 9.47)	0.61‡
medium care	4 (0.7%)	4 (0.6%)	1.06 (0.27 to 4.22)	1.00‡
ward	196 (32.1%)	209 (32.3%)	0.99 (0.85 to 1.17)	0.93
Indications for maternal admission				
Thromboembolic complications	0 (0.0%)	0 (0.0%)	n/a	-
Hypertensive disorders§	3 (0.5%)	13 (2.0%)	0.24 (0.07 to 0.85)	0.02‡
Post-partum blood loss	34 (5.6%)	40 (6.2%)	0.90 (0.58 to 1.40)	0.64
Post-caesarean	71 (11.6%)	74 (11.4%)	1.02 (0.75 to 1.38)	0.92
Pain treatment during labour	309 (50.6%)	278 (43.0%)	1.18 (1.05 to 1.33)	0.007
Remifentanyl	93 (15.2%)	89 (13.8%)	1.11 (0.85 to 1.45)	0.46
Pethidine / phenergan / other opiates	47 (7.7%)	33 (5.1%)	1.51 (0.98 to 2.32)	0.06
Epidural / spinal	194 (31.4%)	173 (26.6%)	1.19 (1.00 to 1.41)	0.05
Others	1 (0.2%)	4 (0.6%)	0.26 (0.03 to 2.36)	0.38‡

19 **(Adverse) maternal outcomes (per-protocol).** *Defined as post-partum haemorrhage ≥ 1000 mL, and/or
20 manual removal of placenta, and/or third or fourth degree tears (Obstetrical Anal Sphincter Injuries, OASIS),
21 and/or intensive care admission, and/or maternal death. Denominator for perineal tear are vaginal deliveries
22 only. †Mann Whitney U test. ‡Fisher's exact test. §Including (pre-)eclampsia, and HELLP syndrome.

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