

When to induce for overweight? – a randomised controlled trial

Acronym: WINDOW

Statistical Analysis Plan (SAP)

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SAP revision history:

SAP version	Description and reasons for change	Date changed
2.0	- Analyses further elaborated for clarity and detail	July 2, 2024
3.0	- Minor variable adjustments made - Adherence more clearly defined - Primary and secondary outcome elaborated in greater detail - Per-protocol and as-treated analyses described in greater detail - Number needed to treat analysis outlined - Childbirth experience outcome analysis outlined - Table shells added to structure results reporting	June 22, 2026

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Abbreviations

BMI:	Body mass index
CI:	Confidence Interval
CPAP:	Continuous Positive Airway Pressure
CTG:	Cardiotocography
CS:	Caesarean section
DMEC:	Data Monitoring and Ethics Committee
eCRF:	electronic Case Record Form
IOL:	Induction of Labour
GDM:	Gestational Diabetes Mellitus
HNFC:	High-Flow Nasal Cannula
NICU:	Neonatal Intensive Care Unit
NNT:	Number needed to treat
RCT:	Randomised Controlled trial
REDCap:	Research Electronic Data Capture
RR:	Risk Ratio
SAP:	Statistical Analysis Plan
sBE:	Standard Base Excess
TSC:	Trial Steering Committee
WHO:	World Health Organisation

1. Trial objective

1.1 Primary objective

- To compare the risk of caesarean section with induction of labour (IOL) versus expectant management of pregnancy in women with a pre- or early pregnancy BMI ≥ 30 kg/m².

P – Pre- or early pregnancy BMI ≥ 30 kg/m²

I – Induction of labour at 39 gestational weeks and 0 to 3 days

C – Expectant management until induction from 41 gestational weeks

O – Caesarean section

1.2 Secondary objectives covered by these analyses

- To compare the effect of IOL at 39 gestational weeks and expectant management on maternal and neonatal morbidity (specified below) and mortality.
- To compare the effect of IOL at 39 gestational weeks and expectant management on women's birth experience (specified below).

1.3 Secondary objectives for planned future analyses

An additional statistical analysis plan will be provided later to cover the planned future analyses.

- To compare the effect of IOL at 39 gestational weeks and expectant management on women's mental health in the postpartum period.
- To compare the effect of IOL at 39 gestational weeks and expectant management on breast feeding.
- To compare the effect of IOL at 39 gestational weeks and expectant management on health resource utilization.
- To compare the effect of IOL at 39 gestational weeks and expectant management on long-term maternal and paediatric outcomes.

2. Trial methods

2.1 Trial design

Multicentre randomised controlled trial parallel group with an allocation ratio of 1:1.

2.2 Trial interventions

Management strategies:

- *Intervention arm; induction of labour in pregnancy at 39 gestational week and 0 to 3 days*
Induction is performed according to local policy for IOL (Prostaglandin E1, E2, Foley catheter, cervical ripening balloon catheter, artificial rupture of membranes (AROM), or oxytocin infusion when applicable). All methods and/or medications are approved for IOL.
- *Comparison arm; expectant management*
Waiting for spontaneous onset of labour unless a clinical situation necessitates IOL or caesarean section. All women with prolonged pregnancy can be offered IOL from 41 gestational weeks and 0 days in accordance with local policy.

2.3 Outcome measures and characteristics

2.3.1 Primary outcome

- Caesarean section

2.3.2 *Secondary maternal outcomes*

- Instrumental delivery
- Indication for caesarean section (more than one is possible):
 - Labour dystocia
 - Foetal distress
 - Maternal request
 - Suspected macrosomia
 - Non-cephalic presentation
 - Extensive vaginal bleeding
 - Suspected uterine rupture
 - Maternal or foetal complication/condition
 - Other
- Indication for vaginal assisted delivery (more than one is possible):
 - Labour dystocia
 - Foetal distress
 - Maternal request
 - Other
- Use of epidural
- Maternal fever defined as temperature $>38,2$ / $>38,0$ °C with / without epidural
- Minor shoulder dystocia defined as the need McRoberts manoeuvre only
- Major shoulder dystocia defined as the need for procedures other than McRoberts manoeuvre
- Abruptio of the placenta leading to an intervention in labour
- Cord prolapse
- Perineal 3rd degree or 4th degree laceration
- Episiotomy
- Postpartum haemorrhage defined as vaginal bleeding in the time frame 0-2 hours postpartum
 - Blood loss >500 ml from a vaginal bleeding in the time frame 0-2 hours postpartum
 - Blood loss >1000 ml from a vaginal bleeding in the time frame 0-2 hours postpartum
 - Blood transfusion within 2 days postpartum
 - Hysterectomy caused by delivery complications
- Uterine scar dehiscence or rupture
- Surgical injury to internal organs including bladder, bowel or ureters
- Puerperal infection treated in hospital
- Other severe postpartum complications (extending to thromboembolic events, acute colon pseudo-obstruction, or other)
- Admission to Intensive Care Unit
- Maternal cardiopulmonary arrest
- Maternal death

2.3.3 Neonatal outcomes

- Neonatal composite including any of the following; perinatal death (stillbirth and neonatal), the need for respiratory support (intubation and mechanical ventilation, non-invasive ventilation, oxygen supplementation, continuous positive airway pressure (CPAP), or high-flow nasal cannula (HNFC)) within 72 hours after birth if admitted to a neonatal department, Apgar score <4 at 5 minutes, moderate to severe hypoxic–ischemic encephalopathy (defined as the need for therapeutic hypothermia), neonatal seizures, infection (defined as antibiotic treatment continuously for 7 days minimum), meconium aspiration syndrome, birth trauma (bone fracture, Duchenne-Erbs palsy, or retinal haemorrhage), intracranial or subgaleal haemorrhage, or hypotension requiring vasopressor support.

Time frame: From randomisation during delivery hospitalisation until 28 days of life

All components of the neonatal composite outcome will also be reported separately.

- Neonatal trauma composite including any of the following; birth trauma (bone fracture, Duchenne-Erbs palsy, or retinal haemorrhage), intracranial or subgaleal haemorrhage.

Time frame: From birth during delivery hospitalization until 28 days of life

- Neonatal asphyxia composite including any of the following; neonatal seizures, Apgar score < 4 at 5 minutes, umbilical cord pH < 7.0, umbilical cord sBE < -15.0 mmol/l, or hypoxic–ischemic encephalopathy (defined as the need for therapeutic hypothermia).

Time frame: From birth during delivery hospitalisation until 28 days of life

- Apgar score <4 at 5 minutes. Time frame: At 5 minutes following birth
- Apgar score 4-6 at 5 minutes. Time frame: At 5 minutes following birth
- Umbilical cord arterial pH < 7.0. Time frame: At birth
- Umbilical cord arterial standard base excess value (sBE) < -15.0 mmol/l. Time frame: At birth
- Umbilical cord venous pH < 7.0. Time frame: At birth
- Umbilical cord venous standard base excess value (sBE) < -15.0 mmol/l. Time frame: At birth
- Neonatal Intensive Care Unit admission. Time frame: Within 72 hours after birth
- Treatment during admission. Time frame: From admission during delivery hospitalisation until 28 days of life
 - CPAP
 - HNFC
 - Oxygen supplement treatment
 - Ventilator treatment
 - Therapeutic hypothermia
 - Vasopressor support
 - Antibiotic treatment continuously for 7 days' minimum

2.3.4 Maternal experience on birth

- Birth experience (Childbirth Experience Questionnaire, CEQ1)(1).
Time frame: 4-6 weeks postpartum

2.3.5 Maternal demographics and pregnancy characteristics

- Pre- or early gestational BMI
- Pre- or early gestational weight
- Height
- Parity
- Age
- Nationality of origin
- Married or living with a partner
- Employment status
- Level of education
- Assisted conception
- Current smoking status
- Gestational diabetes mellitus treated by diet alone
- Length of gestation at randomisation – weeks + days

2.3.6 Labour and birth characteristics

- Gestational age at delivery – weeks + days
- Onset of labour:
 - Spontaneous labour
 - Induced labour
 - Caesarean section before labour onset
- Gestational age at onset of labour – weeks + days
- If induction of labour; Indications for induction of labour (more than one category possible):
 - Randomised to induction
 - Prolonged pregnancy
 - Pre- or early pregnancy BMI ≥ 35 kg/m²
 - Hypertensive disorder of pregnancy
 - Suspicion of foetus magnus
 - Maternal request
 - Other
- If induction of labour; Method of induction of labour (more than one category possible):
 - Prostaglandin tablet
 - Prostaglandin vaginal pad
 - Foley catheter
 - Cervical ripening catheter
 - Oxytocin infusion for induction
 - Artificial rupture of membranes and not augmentation of labour
 - Other
- If induction of labour; Number of complete 24-hour periods without induction interventions and reasons for pause
- If induction of labour; Time from induction of labour until delivery (days)
- Cervical dilation at delivery ward admission
- Foetal head station at delivery ward admission
- Cervix length at delivery ward admission
- If caesarean; urgency of caesarean

- Emergency caesarean before labour onset
- Scheduled caesarean before labour onset
- Emergency caesarean during labour before a previously scheduled caesarean
- Emergency caesarean during labour
- If caesarean; Cervical dilation at caesarean section
- If caesarean; Fetal head station at caesarean section
- If caesarean; Cervix length at caesarean section
- Use of oxytocin augmentation during labour

2.3.7 Neonatal characteristics

- Birthweight (continuous; in grams)
- Birthweight > 4500 grams
- Sex (boy/girl)

2.4 Data collection and data management

Data will be collected and managed using REDCap electronic data capture tools hosted at Aarhus University. REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

Except from some of the baseline data and data from the post-partum questionnaires, all data will be obtained from the in-hospital electronic medical record.

- Data collection methods; Data will be collected in electronic case record forms (eCRFs) on which almost every response is pre-coded. The forms are generated using REDCap.
- If participants discontinue or deviate from the intervention protocol, we will continue to collect data, unless the woman specifically state that we cannot collect or store her data.

2.5 Randomisation

- Sequence generation and concealment; Eligible women will be randomised using an Internet-based randomisation programme in a 1:1 ratio using permuted and random block-sizes of 2, 4, and 6. There will be stratification on delivery site. The randomisation programme will automatically transfer the entry data to eCRFs in REDCap.
- Implementation; The allocation sequence is pre-coded and generated from the randomisation programme.

2.6 Criteria for discontinuation

Withdrawal of consent.

2.7 Blinding

The trial is open label.

2.8 Sample size

The planned sample size is 1,900 (950 per group).

For the primary outcome, the sample size is based on an assumed caesarean section rate in the non-intervention group of 25%, which was the caesarean section rate among women with a pre- or early pregnancy BMI ≥ 30 kg/m² who delivered at Aarhus University Hospital in 2018. Assuming a caesarean section rate in the intervention group of 19%, 854 participants are needed in each group to detect a difference in caesarean section risk in the two groups with a power of 85% (alpha 0.05). Allowing for 10% dropout results in 950 in each group.

2.9 Framework

The objective of this trial is to test superiority of one intervention to another. The null hypothesis is that there is no difference in the rate of caesarean section between women allocated to IOL at 39 gestational weeks versus expectant management.

2.10 Interim analysis and stopping rules

No interim analysis is planned, and there will be no formal stopping criteria.

An independent data monitoring and ethics committee (DMEC) are appointed prior to initiation of the trial. The DMEC will review de-identified data for safety at two predetermined milestones (600 and 1300 enrolled participants) but can – at any time – require extra reviews. The trial will continue while the DMEC reviews data. After the review, the DMEC will create a short report to the independent trial steering committee (TSC) with recommendations for continuation with or without modifications or termination of the trial. Recommending termination will be at the discretion of the DMEC, and there will be no formal statistical criteria for termination due to safety.

3. Statistical principles

3.1 Analysis population

All main statistical analyses will be based upon the total cohort of participants randomised into the trial. Data will be analysed according to the intention-to-treat principle.

3.2 Definition of adherence

Intervention group: The following will be considered non-adherent: Women giving birth or receiving IOL prior to 39 gestational weeks and 0 days; women still pregnant after 39 gestational weeks and 3 days who have not received IOL; Women receiving IOL initiated between 39 gestational weeks and 0 days and 39 gestational weeks and 3 days with IOL subsequently interrupted or discontinued for 48 hours or more without any induction interventions. All other will be considered adherent.

Comparison group: The following will be considered non-adherent: Women giving birth or receiving IOL prior to 39 gestational weeks and 0 days. All other will be considered adherent.

3.3 Loss to follow-up

Loss to follow-up is defined as no information on mode of delivery.

4. Trial population

4.1 Recruitment

Participant flow will be presented in a CONSORT flow diagram (Figure 1).

4.2 Baseline and other descriptive characteristics

Baseline characteristics will be presented as in Table 1 with counts and percentages for categorical variables, and median with interquartile interval (Q1-Q3) for continuous variables. Tests for statistical significance in baseline characteristics between the groups will not be undertaken, nor confidence intervals presented.

Characteristics of labour onset will be presented as in Table 2.

Characteristics regarding IOL and caesarean sections will be presented as in Supplementary Table 1.

Neonatal characteristics will be presented as in Supplementary Table 2.

5. Analysis methods

For all analyses, two-sided P-values < 0.05 will be interpreted as statistically significant.

5.1 Analysis of the primary outcome

The number of events and absolute risk of the primary outcome will be presented for each of the two groups (intervention and comparison); absolute risks will be computed as simple proportions and reported without confidence intervals (CIs).

The two groups will be compared with respect to the primary outcome variable using a random effects log-binomial model, including the randomisation variable as a fixed effect and delivery site as a random intercept (Table 3). (2) The risk ratio (RR) with 95% CI and a p-value for the null hypothesis of no difference in risk will be reported.

If the model does not converge, i.e., the software returns an error, the groups will be compared using a random effects logistic model including the same variables. If this model does not converge, the groups will be compared using a logistic model with site of birth included as a fixed effect, and ultimately if this model does not converge, delivery site will be removed from the model. The parameters from the (random or fixed effect) logistic regression model will then be used to estimate a risk ratio by marginalisation with confidence intervals computed using the delta method. (3)

The number needed to treat (NNT) will be calculated as the inverse of the absolute risk difference, which will be derived from the log-binomial or logistic regression model via marginalisation (Supplementary Table 3). The confidence interval for the risk difference will be computed using the delta method. The limits of 95% CI for the NNT will be obtained by taking the inverse of the upper and lower limits of the 95% CI for the absolute risk difference, with limits transposed accordingly. (4) The NNT will only be reported if the risk difference is statistically significantly different from 0.

5.2 Analyses of secondary binary outcomes

The number with the individual secondary outcome along the associated risks will be reported for each group, as for the primary outcome (Tables 3 and 4).

The secondary outcomes will be compared across groups in the same way as the primary outcome, however, only if events are observed in both groups: random effect log-binomial models will be fitted for each outcome; if a model does not converge, a random effects logistic model (followed by a fixed effects model, then a model without site if convergence continues to fail) will be fitted instead and used to obtain a risk ratio by marginalisation.

5.3 Analysis of childbirth experience outcome

The childbirth experience questionnaire covers three domains: “Own capacity”, “Participation” and “Professional support” each consisting of a list of items scored 1-4 (Table 5). Each domain will be analysed separately; women answering at least half the questions within a domain will be included for that domain, and their domain value will be set to the sum of item scores divided by the number of questions answered. Furthermore, an “Overall” score will be computed using all items; here, women answering at least half the questions will be included and their score will be computed as for each domain. The mean value for each group will be computed along with the standard deviation, and the groups will be compared using a linear random effects model, including the randomisation group as a fixed effect and delivery site as a random intercept.

5.4 Planned subgroup analyses

We will conduct the following subgroup analyses for the primary outcome (Figure 2):

- BMI $\leq$ or $\geq$ 35 kg/m²
- Parity 0 versus 1+
- No gestational diabetes mellitus (GDM) versus GDM

For these analyses, the subgroup indicator and an interaction term between the randomisation variable and the subgroup indicator will be included in separate random effect log-binomial models. If a model does not converge, a random effects logistic regression model (subsequently: a fixed effects model and a model without delivery site, in case of non-convergence) will be run, and the parameters will be used for marginalisation to obtain measures on the risk-ratio scale.

5.5 Supportive analyses

Supportive analyses (Supplementary Table 4) will consist of

- A per-protocol analysis restricting to adherent women (see section 3.2) for the primary outcome only.
- An as-treated analysis for the primary outcome only. In the as-treated analysis, all women non-adhering due to birth or IOL prior to gestational week 39+0 will be excluded. Women in the intervention group non-adhering due to IOL after 39+3 or discontinued IOL will be analysed as if they belong to the control group.

For the supportive analyses adjustment will be made for the following potential confounders; Pre-pregnancy BMI (continuous; included as a linear term), smoking status, level of education,

GDM, parity (P0, P1, P>1), maternal age (continuous; included as a linear term), delivery site, year of enrolment (categorical). Missing status will be considered a separate group for categorical variables. The randomisation variable and the above potential confounding factors will be included as fixed effects in log-binomial models, if these do not converge the variables will be included in a logistic regression model, and marginalisation will be used to estimate risk ratios from the logistic regression models.

5.6 Missing data

Analyses will be completed on received data only with every effort made to follow-up participants to minimise any potential for bias. No imputation of missing data will be performed.

5.7 Statistical software

We will use R version 4.5.0 or higher and/or SAS version 9.4 or higher for data management and analyses.

References

1. Dencker A, Taft C, Bergqvist L, Lilja H, Berg M. Childbirth experience questionnaire (CEQ): development and evaluation of a multidimensional instrument. *BMC Pregnancy Childbirth*. 2010;10:81.
2. Kahan BC. Accounting for centre-effects in multicentre trials with a binary outcome - when, why, and how? *BMC Med Res Methodol*. 2014;14:20.
3. Arel-Bundock V, Greifer N, Heiss A. How to Interpret Statistical Models Using marginaeffects for R and Python. *Journal of Statistical Software*. 2024;111(9):1 – 32.
4. Altman DG. Confidence intervals for the number needed to treat. *Bmj*. 1998;317(7168):1309–12.

Figures and tables

Figure 1. CONSORT flow diagram

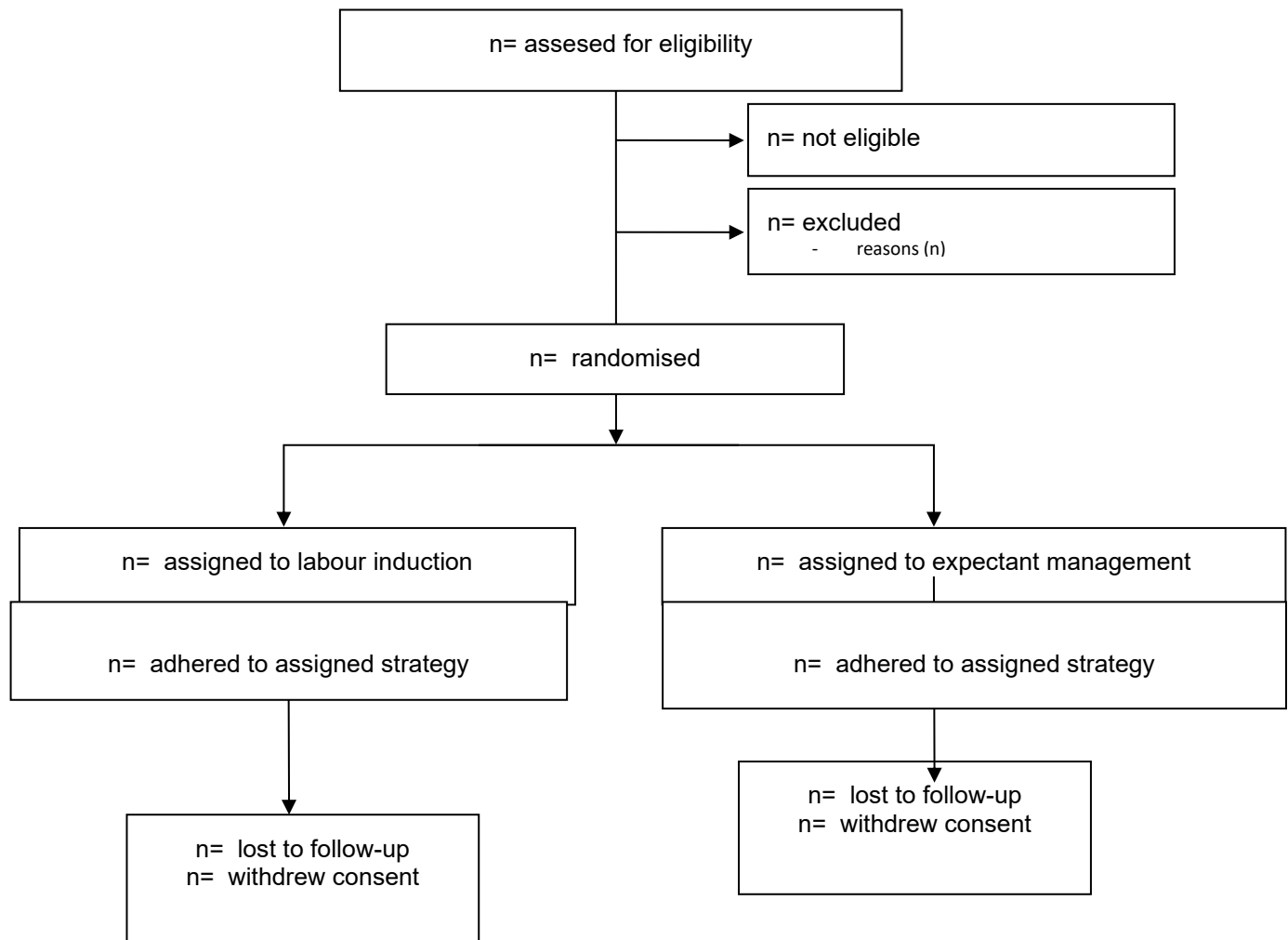


Table 1. Maternal characteristics at baseline.		
Characteristic	IOL Group (n=)	Expectant management group (n=)
Pre- or early gestational BMI*		
Median	-	-
Interquartile interval	-	-
30 to 34 – no. (%)	-	-
35 to 39 – no. (%)	-	-
40 or more – no. (%)	-	-
Pre- or early gestational weight – kg		
Median	-	-
Interquartile interval	-	-
Height – meters		
Median	-	-
Interquartile interval	-	-
Parity		
P0 – no. (%)	-	-
P1 – no. (%)	-	-
P more than 1 – no. (%)	-	-
Age – yr		
Median	-	-
Interquartile interval	-	-
Nationality of origin		
Danish national origin – no. (%)	-	-
Other national origin – no. (%)	-	-
Married or living with a partner – no. (%)	-	-
Employment status		
Studying – no. (%)	-	-
Employed – no. (%)	-	-
Not employed – no. (%)	-	-
Employment status unknown – no. (%)	-	-
Level of education**		
State school – no. (%)	-	-
High school – no. (%)	-	-
Vocational education – no. (%)	-	-
Short further education (≤ 2 yr) – no. (%)	-	-
Medium further education (2-4 yr) – no. (%)	-	-
Long further education (> 4 yr) – no. (%)	-	-
Assisted conception – no. (%)	-	-
Current smoking status – no. (%)	-	-
GDM*** – no. (%)	-	-
Length of gestation at randomization – weeks + days		
Median	-	-
Interquartile interval	-	-

BMI is the weight in kilograms divided by the square of the height in meters; **Level of education is self-reported; *Only GDM treated by diet alone is registered hence GDM treated by insulin is excluded. Induction of labor (IOL), Body-mass index (BMI), Gestational diabetes mellitus (GDM), Years (yr)*

Table 2: Characteristics of labour onset.

Characteristics	IOL Group (n=)	Expectant Management Group (n=)
Onset of labour		
Spontaneous labour – no. (%)	-	-
Induced labour – no. (%)	-	-
Caesarean section before labour onset – no. (%)	-	-
Gestational age at onset of labour – weeks + days		
Median	-	-
Interquartile interval	-	-
Indication for IOL*		
Randomised to induction – no. (%)	-	-
Prolonged pregnancy – no. (%)	-	-
BMI of 35 kg/m ² or more – no. (%)**	-	-
Hypertensive disorder of pregnancy – no. (%)	-	-
Suspicion of foetus magnus – no. (%)	-	-
Maternal request – no. (%)	-	-
Other – no. (%)	-	-

**More than one indication per participant possible; **BMI is the weight in kilograms divided by the square of the height in meters. Induction of labour (IOL); Body mass index (BMI)*

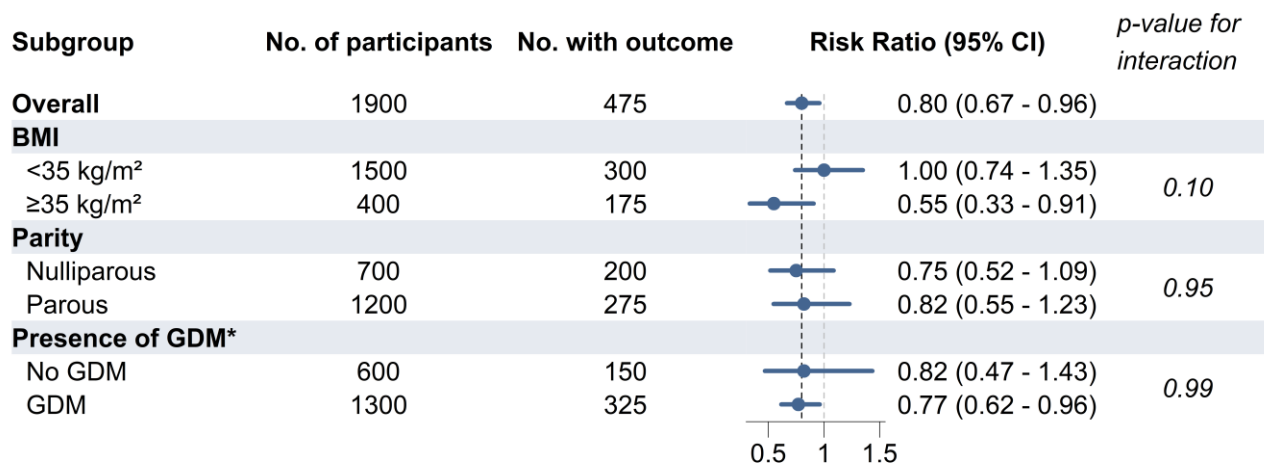
Table 3: Maternal outcomes.				
Outcome	IOL group (n=)	Expectant management group (n=)	RR (95%CI)	P Value
Method of delivery – no. (%)				
Caesarean section	-	-	-	-
Instrumental delivery	-	-	-	-
Indication for caesarean section – no. (%)				
Labor dystocia	-	-	-	-
Foetal distress	-	-	-	-
Maternal request	-	-	-	-
Suspected macrosomia	-	-	-	-
Non-cephalic presentation	-	-	-	-
Extensive vaginal bleeding	-	-	-	-
Suspected uterine rupture	-	-	-	-
Maternal medical complication	-	-	-	-
Other	-	-	-	-
Indication for assisted vaginal delivery – no. (%)				
Labor dystocia	-	-	-	-
Foetal distress	-	-	-	-
Maternal request	-	-	-	-
Other	-	-	-	-
Use of epidural – no. (%)	-	-	-	-
Intrapartum fever* – no. (%)	-	-	-	-
Minor shoulder dystocia** – no. (%)	-	-	-	-
Major shoulder dystocia*** – no. (%)	-	-	-	-
Abruption of the placenta**** – no. (%)	-	-	-	-
Cord prolapse – no. (%)	-	-	-	-
Perineal 3 rd and 4 th degree laceration – no. (%)	-	-	-	-
Episiotomy – no. (%)	-	-	-	-
Postpartum haemorrhage [^] – no. (%)				
Blood loss >500ml	-	-	-	-
Blood loss >1000ml	-	-	-	-
Blood transfusion	-	-	-	-
Hysterectomy – no. (%)	-	-	-	-
Uterine scar dehiscence or rupture – no. (%)	-	-	-	-
Damage to internal organs ^{^^} – no. (%)	-	-	-	-
Puerperal infection ^{^^^} – no. (%)	-	-	-	-
Other severe postpartum conditions ^{^^^^} – no. (%)	-	-	-	-
Admission to ICU – no. (%)	-	-	-	-
Cardiopulmonary arrest – no. (%)	-	-	-	-
Death – no. (%)	-	-	-	-
<i>*Defined as temperature >38.2°C with epidural, without epidural: >38.0°C; **Defined as the need McRoberts manoeuvre; ***Defined as the need for procedures other than McRoberts manoeuvre; ****Defined as clinical suspicion leading to an intervention in labour; ^Estimated postpartum haemorrhage within the first 48 hours from birth; ^^Defined as bladder, bowel and ureters; ^^^Defined as puerperal infection treated in hospital; ^^^^^Severe postpartum conditions treated in hospital besides puerperal infections, including any thromboembolic event. Induction of labour (IOL), Relative risk (RR), Confidence interval (CI), Intensive Care Unit (ICU).</i>				

Table 4: Neonatal outcomes.				
Outcome	IOL group (n=)	Expectant management group (n=)	RR (95%CI)	P Value
Neonatal composite outcome – no. (%)	-	-	-	-
Perinatal death (stillbirth or neonatal)	-	-	-	-
Respiratory support*	-	-	-	-
Apgar scores <4 at 5 min	-	-	-	-
Moderate to severe hypoxic ischemic encephalopathy**	-	-	-	-
Seizures	-	-	-	-
Infection***	-	-	-	-
Meconium aspiration syndrome	-	-	-	-
Birth trauma****	-	-	-	-
Intracranial or subgaleal haemorrhage	-	-	-	-
Hypotension ^	-	-	-	-
Trauma composite outcome – no. (%)	-	-	-	-
Asphyxia composite outcome – no. (%)	-	-	-	-
Umbilical cord arterial pH <7.0 – no. (%)	-	-	-	-
Umbilical cord arterial base excess <-15.0 mmol/L – no. (%)	-	-	-	-
Umbilical cord venous pH <7.0 – no. (%)	-	-	-	-
Umbilical cord venous base excess <-15.0 mmol/L – no. (%)	-	-	-	-
Apgar scores from 4 to 6 at 5 min – no. (%)	-	-	-	-
NICU admission^^ – no. (%)	-	-	-	-
Treatment if NICU admission – no. (%)	-	-	-	-
CPAP	-	-	-	-
HNFC	-	-	-	-
Oxygen supplement treatment	-	-	-	-
Ventilator treatment	-	-	-	-
Therapeutic hypothermia	-	-	-	-
Vasopressor support	-	-	-	-
Antibiotic treatment^^^	-	-	-	-

Defined as the need for respiratory support (intubation and mechanical ventilation, oxygen, continuous positive airway pressure (CPAP), or high-flow nasal cannula (HNFC)) within 72 hours after birth if admitted to Neonatal Intensive Care Unit (NICU); **Defined as the need for therapeutic hypothermia; *Defined as antibiotic treatment continuously for 7 days minimum; ****Defined as any fracture, Duchenne-Erbs palsy, or retinal hemorrhage; ^Defined as hypotension requiring vasopressor support; ^^Defined as NICU admission within 72 hours from birth; ^^^Defined as antibiotic treatment administered continuously for 7 days minimum. Induction of labor (IOL), Relative risk (RR), Confidence interval (CI), Minutes (min), Grams (g).*

Table 5: Childbirth experience*				
Domain	IOL group	Expectant management group	Mean difference (95%CI)	P Value
Own capacity	-	-	-	-
Participation	-	-	-	-
Professional support	-	-	-	-
Overall score	-	-	-	-
*Mean (standard deviation) Childbirth Experience Questionnaire scores on scale from 1 to 4, with 4 being optimum.				

Figure 2: Subgroup analyses (mock-up, numbers do not reflective the collected data)



*Only GDM treated by diet alone is registered hence GDM treated by insulin is excluded. Relative risk (RR), Confidence interval (CI), Body mass index (BMI), Gestational diabetes mellitus (GDM).

Supplementary tables

Supplementary Table 1. Labour and birth characteristics.		
Characteristic	IOL Group (n=)	Expectant management group (n=)
Cervical dilation at delivery ward admission		
Closed	-	-
1 – 2 cm	-	-
3 – 4 cm	-	-
> 4 cm	-	-
Foetal station at delivery ward admission		
-3	-	-
-2	-	-
-1 - 0	-	-
+1 - +2	-	-
Cervix length at delivery ward admission		
3 cm	-	-
2 cm	-	-
1 cm	-	-
0 cm	-	-
Use of oxytocin augmentation during labour	-	-
Induction of labour		
Method of induction of labour		
Prostaglandin tablet	-	-
Prostaglandin vaginal pad	-	-
Foley catheter	-	-
Cervical ripening catheter	-	-
Oxytocin infusion for induction	-	-
Artificial rupture of membranes and not augmentation of labour	-	-
Other	-	-
Number of whole days (24 h) without induction interventions		
1 day	-	-
2 days	-	-
Reason for pause		
Patients demand/wish	-	-
Professional reason	-	-
Logistic considerations	-	-
Reason unclear	-	-
Time from induction of labour until delivery (days)		
Median	-	-
Interquartile interval	-	-
Caesarean section		
Urgency of caesarean section		
Emergency caesarean before labour onset	-	-
Scheduled caesarean before labour onset	-	-

Emergency caesarean during labour before a previously scheduled caesarean	-	-
Emergency caesarean during labour	-	-
Cervical dilation at caesarean section		
0 – 4 cm	-	-
5 – 6 cm	-	-
7 – 10 cm	-	-
Foetal station at caesarean section		
-3	-	-
-2	-	-
-1 - 0	-	-
+1 - +2	-	-
Cervix length at caesarean section		
3 cm	-	-
2 cm	-	-
1 cm	-	-
0 cm	-	-
<i>Induction of labour (IOL)</i>		

Supplementary Table 2. Neonatal characteristics.		
Characteristic	IOL group (n=)	Expectant management group (n=)
Birthweight – grams		
Median	-	-
Interquartile interval	-	-
Birthweight > 4500 grams	-	-
Sex (boy / girl)	-	-

Supplementary Table 3: Primary outcome; number needed to treat.	
Outcome	NNT (95%CI)
Method of delivery	
Caesarean section	-
<i>Number needed to treat (NNT), Confidence interval (CI).</i>	

Supplementary Table 4: Primary outcome; supportive analyses.				
	IOL group (n=)	Expectant management group (n=)	RR (95%CI)	P Value
Outcome				
Per-protocol – no. (%)	-	-	-	-
As-treated – no. (%)	-	-	-	-
<i>Risk ratio (RR), Confidence interval (CI)</i>				