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Comparing different concentrations of oxytocin to augment slow labour in obese mothers

Submission date
07/04/2025

Registration date
09/04/2025

Last Edited
07/04/2025

Recruitment status
Recruiting

Overall study status
Ongoing

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
Worldwide between 1980 and 2013, the proportion of overweight adult women increased from 29.8% to 38.0%; this trend is continuing. By 2014, more than half of pregnant women were overweight, and nearly a third were obese in many countries. Pregnant women who are obese have a slower progression of labor and of not making progress in labour, such that a body mass index increment of 1 (BMI: a measure of body weight in kilograms to the square of height in meters) caesarean section risk by increased by a relative 10%. Oxytocin is a hormone (a substance naturally produced by the body) which is also available as a medication administered by drip to start or strengthen inadequate uterine contractions. The oxytocin drip is currently commonly used during care in labour. Once started to help with womb contractions, the oxytocin drip is usually maintained until the birth of the baby. Obesity in pregnancy is common and increasingly so; the caesarean delivery rate is similarly increasing. Many instances of caesarean delivery during labour are because of slow or no progress. This study addresses whether, in patients who are obese, a higher concentration of oxytocin solution when labour is slow can be more efficient in overcoming that issue.

Who can participate?
Women aged 18-45 years, who are at least 37 weeks pregnant, experiencing spontaneous labor with contractions and cervical dilation, have a BMI of 27.5 kg/m² or higher, and have not had a previous pregnancy lasting 22 weeks or more.

What does the study involve?
This is a double blind randomized clinical trial, meaning that neither the participants nor their doctor can choose or will know which concentration of oxytocin solution they will be allocated to. The allocation process is generated by a computer.

This study evaluates the use of oxytocin solutions of different concentrations (the standard concentration and 1.5 times the standard concentration) in patients who need an oxytocin drip in their labour. The starting drip rate is the same in both groups. The regimen for adjusting the drip rate is also the same. The drip rate will be periodically adjusted to attain a womb contraction rate of 3 to 4 moderate-to-strong contractions every 10 minutes. The womb contraction rate will be continuously monitored electronically until birth. The same maximum

drip rate will be set for both groups. The purpose of the study is not necessarily to give a higher overall oxytocin dose to patients, as the drip rate is guided by the womb contraction response. The drip rate will not be further increased once the desired contraction rate has been achieved and sustained. However, the use of the 1.5 times higher concentration solution can result in the starting drip dosing, the drip dosing step wise increment and the maximum drip dosing being potentially 1.5 times greater. Participants will be included in the study if their doctor decides that they need the oxytocin drip. The oxytocin solution used will be 1.5 times standard or standard strength, as randomly allocated. The drip will be used and adjusted in the usual manner. Standard care for labour will be provided, including any decision-making. Participants will be asked to provide a satisfaction score on their use of a simple 0-10 numerical rating scale after the birth of their baby.

What are the possible benefits and risks of participating?
A quicker labour and faster birth from using a higher concentration oxytocin solution may lead to positive consequences on the need for caesarean delivery, infection, childbirth-related bleeding and maternal experience of childbirth and mother-baby bonding.

Oxytocin increases the frequency and strength of womb contractions. It is possible that contractions can become too frequent and too strong. Oxytocin has a short duration of action implying that its impact on contractions can quickly disappear on reducing or stopping the drip. Medicines are also available to get the uterus to relax if needed. Womb contractions will be continuously monitored electronically. It is not expected but possible that actions that are too frequent and too strong can result in the recommendation to perform a caesarean section if the baby is showing signs of distress. Participants can withdraw from the study at any time without having to provide any reason. Their care will not be affected in any way. Usual care will be provided.

Where is the study run from?
Department of Obstetrics and Gynaecology, Universiti Malaya Medical Centre (UMMC).

When is the study starting and how long is it expected to run for?
June 2024 to June 2026

Who is funding the study?
Department of Obstetrics and Gynaecology, Universiti Malaya Medical Centre (UMMC).

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
RSCH ID-25-01040-YE3

Study information

Scientific Title
High vs. standard concentration oxytocin solution for labour augmentation in obese multiparas: a double blind randomized controlled trial

Acronym
HiSOLA

Study objectives
Use of a 1.5 times higher concentration oxytocin solution to augment labour in obese mothers with prior vaginal birth will expedite birth

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/02/2025, University Malaya Medical Centre - Medical Research Ethic Committee (UMMC-MREC) (Jln Profesor Diraja Ungku Aziz, Seksyen 13, Petaling Jaya, Wilayah Persekutuan Kuala Lumpur, 50603, Malaysia; +60 0379498473; ummc-mrec@ummc.edu.my), ref: 20241219-14500

Study design
Single-centre parallel-group double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Labour dystocia (abnormal labour progress)

Interventions
A randomisation sequence is generated using an online randomiser in blocks of 4 or 8 (1-to-1 ratio) by an investigator not involved in study recruitment. Participants will be randomised by the opening of numbered sealed opaque envelopes (the lowest-numbered envelope remaining allocated to the newest recruit) to the following interventions:
a) Oxytocin 15 IU in 500 ml Hartmann's solution (1.5 times the concentration solution). Infusion to start at 6 ml/hr (3 mIU/min), infusion rate to be doubled every 30 minutes to achieve 3- 4 moderate-strong uterine contractions every 10 minutes. Once the response of 3-4 contractions every 10 minutes is achieved, the infusion rate will be maintained to birth if there is no interim event requiring dose adjustment. Maximum infusion rate of 96 ml/hr (48 mIU/min). Maximum infusion rate of 96 ml/hr (48 mIU/min).
OR
b) Oxytocin 10 IU in 500 ml Hartmann's solution (standard concentration solution). Infusion to start at 6 ml/hr (2 mIU/min), infusion rate to be doubled every 30 minutes to achieve 3- 4 moderate-strong uterine contractions every 10 minutes. Once the response of 3-4 contractions every 10 minutes is achieved, the infusion rate will be maintained to birth if there is no interim event requiring dose adjustment. Maximum infusion rate of 96 ml/hr (32 mIU/min).
In both arms, the regimen of infusion rate adjustment is thus standardised. The aim is to arrive at the lowest oxytocin infusion rate capable of sustaining 3-4 uterine contractions every 10 minutes. The concentration of the oxytocin solution will be masked from care providers, participants and outcome assessors.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Oxytocin

Primary outcome(s)
Start of oxytocin infusion to birth interval measured using data collected from the patient's electronic medical record at one timepoint

Key secondary outcome(s))
The secondary outcome measures were assessed from data collected from the electronic medical record at one timepoint, unless stated:

1. Maximum oxytocin infusion rate used
2. Duration of oxytocin infusion
3. Total volume infused
4. Cardiotocographic abnormality (through first stage of labour)-assessed by a blinded assessor
4.1. Tachysystole (contractions ≥6 in 10 minutes)
4.2. Hypertonus (sustained contraction ≥2 minutes)
4.3. Hyperstimulation syndrome (tachysystole and/or hypertonus with concurrent fetal deceleration [defined as a decrease in fetal heart rate of ≥15 bpm from baseline for ≥15 seconds])
5. Number of doses of tocolytic given, if any
6. Mode of delivery
6.1. Spontaneous vaginal
6.2. Vacuum
6.3. Forceps
6.4. Caesarean section
7. Indication for caesarean section
8. Indication for instrumental vaginal delivery
9. Maternal satisfaction with the birth process measured using an 11-point 0-10 NRS – numerical rating scale, after delivery (higher score, greater satisfaction)
10. Blood loss during delivery
11. Third- or fourth-degree tear
12. Maternal infection
13. Intrapartum therapeutic antibiotics (excluding prophylactic antibiotics)
14. Epidural in labour
15. Length of hospital stay
16. ICU admission
17. Cardiorespiratory arrest
18. Needing a hysterectomy

19. Neonatal outcomes
19.1. Apgar score at 1 and 5 minutes
19.2. NICU admission
19.3. Cord pH
19.4. Neonatal sepsis
19.5. Birth weight
19.6. Birth trauma
19.7. Hypoxic ischaemic encephalopathy/need for therapeutic hypothermia

Major harm
20. Neonatal hypoxic ischaemic-encephalopathy requiring cooling therapy due to uterine hyperstimulation syndrome
21. Maternal convulsions due to water intoxication

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. BMI ≥27.5 kg/m2 (Asian definition of obesity)
2. Spontaneous labour (contraction >2:10 minutes and cervical dilatation ≥3cm)

3. Inadequate progress as clinically determined
4. Multiparous (at least one prior vaginal delivery)
5. Term ≥37 weeks gestation
6. Age 18-45 years old
7. Membranes ruptured (including prelabour rupture of membranes)
8. Singleton pregnancy
9. Cephalic presentation
10. Reassuring fetal heart rate tracing at initiation of oxytocin infusion

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
Female

Key exclusion criteria
1. Induced labour (prior Foley, prostaglandin or oxytocin)
2. Previous uterine scar (caesarean/myomectomy/perforation)
3. Known major fetal anomaly
4. Fetal weight clinically estimated to be ≤2 kg & ≥4 kg and subsequently confirmed by ultrasound
5. Grand multiparous (parity ≥5)

Date of first enrolment
15/04/2025

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre (UMMC)
Lembah Pantai

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Sponsor information

Organisation
University Malaya Medical Centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
Universiti Malaya

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. The hardcopy data will be kept in a secure locker with a lock in the Obstetric & Gynaecology Department of UMMC. The keys to the lock will be kept by the primary investigator. The researcher (Muhammad Ariff Bin Saari) and supervisors (Prof Dr Tan Peng Chiong and Prof Dr Aizura) will have access to the research data; these data will be kept for 7 years.

Only the investigators have access to the medical records and research data. Anonymized (where individuals cannot be identified) study data may be released to other researchers in the future as permitted by the Ethics committee. Both paper and electronic records of trial data will be kept confidential. Physical and electronic means will be applied to keep the data secure.

IPD sharing plan summary

Stored in non-publicly available repository, Available on request