ISRCTN87387293 https://doi.org/10.1186/ISRCTN87387293

Membrane sweeping or no membrane sweeping just prior to transcervical Foley catheter insertion for induction of labour in women with one previous caesarean delivery

Submission date
03/06/2020

Recruitment status
Stopped

Registration date
11/06/2020

Overall study status
Stopped

Last Edited
15/12/2021

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
Caesarean delivery is the use of surgery to deliver babies. Pregnancy after a previous caesarean delivery is an increasingly common scenario. In current practice, labour is induced in at least one in five pregnancies. Trial of labour after one caesarean is standard practice. Induction of labour in women with one previous caesarean delivery is an accepted practice in well-motivated women and when conducted in an appropriate care environment with immediate access for urgent caesarean delivery. Starting labour with a Foley balloon is considered to be particularly suitable in women with one previous caesarean delivery as excessive contractions are uncommon with this method. The Foley catheter is inserted into the lower womb through the vagina and cervix and inflated to retain the balloon to allow it to gradually open the cervix. Studies have shown that membrane sweeping just before applying other methods (such as using prostaglandins, artificially rupturing membrane) hastens the birth process resulting in a quicker normal delivery. However, membrane sweeping prior to Foley catheter insertion for labour induction has not been studied in women with one previous caesarean delivery. The aim of this study is to compare transcervical Foley catheter insertion in the induction of labour of women with one previous caesarean with and without membrane sweeping in terms of the time to achieve delivery and participant's satisfaction with their birth process. This study is important as to the researchers' best knowledge there is no information available within a clinical trial context on the effect of membrane sweeping before transcervical Foley catheter as a method of labour induction in women with a previous caesarean.

Who can participate?
Pregnant women with one previous caesarean section who are scheduled for induction of labour

What does the study involve?
Participants will be randomly allocated to one of the treatment groups: induction of labour with transcervical Foley catheter either without membrane sweeping (standard care) or with membrane sweeping. Membrane sweeping involves placing a finger into the slightly opened

cervix and making a circular, sweeping movement to separate the membranes that surround the baby from the lower uterus, at the same time stretching the cervical opening. If the cervix is closed and does not permit the finger to be inserted, the cervix will be massaged instead. The Foley catheter is usually inserted digitally (a vaginal speculum can be used if digital insertion is unsuccessful) into the lower womb. The balloon near the tip is then inflated with 60 ml of sterile water. The catheter will be kept for up to 24 hours, after which the balloon will be deflated and the catheter removed if not already expelled.

What are the possible benefits and risks of participating?
There may or may not be any benefit to participants as it is not known whether membrane sweeping with Foley catheter balloon labour induction is more effective than Foley catheter balloon alone in women who have one previous caesarean delivery. Membrane sweeping can cause some pain, provoke usually self-limiting mild vaginal bleeding or uncommonly may cause the water bag to rupture (this is not a problem as breaking the water bag is part of inducing labour, but alternative methods to balloon insertion will be applied if this happens). Major complications are not anticipated. Membrane sweeping is routinely offered as standard outpatient care to women at full term to help initiate labour and also when labour is being formally induced in combination with other induction methods.

Where is the study run from?
University Malaya Medical Centre (Malaysia)

When is the study starting and how long is it expected to run for?
October 2019 to December 2021

Who is funding the study?
University Malaya Medical Centre (Malaysia)

Who is the main contact?
Dr Vilasini Devi d/o Magalingam
vilash86@hotmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Vilasini Devi Magalingam

Contact details
No.11, Jalan Sunway 6/5
Fasa 6, Bandar Sunway Semenyih
Semenyih
Malaysia
43500
+60 (0)167114063
vilash86@hotmail.com

Type(s)
Scientific

Contact name
Prof Tan Peng Chiong

ORCID ID
http://orcid.org/0000-0001-8713-6581

Contact details
Obstetrics and Gynaecology Department
Women and Children Health Complex
University Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
Malaysia
59100
+60 (0)123052970
pctan@um.edu.my

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2019111-7979

Study information

Scientific Title
Transcervical Foley catheter with and without adjunctive membrane sweeping for induction of labour in women with one previous caesarean delivery: a randomized trial

Study objectives
Adjunctive membrane sweeping just prior to transcervical Foley catheter insertion for induction of labour (IOL) in women with one previous caesarean delivery will shorten the induction to delivery interval and will increase maternal satisfaction with the delivery process.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/02/2020, University Malaya Medical Centre Medical Research Ethics Committee (MREC) (University Malaya Medical Centre, Lembah Pantai, 59100, Kuala Lumpur, Malaysia; +60 (0)3-79494422;
ummc@ummc.edu.my), no ref provided

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Induction of labour in women with one previous caesarean delivery and unripe cervix

Interventions
Randomisation will be done with the opening of the lowest available numbered sealed opaque envelopes in strict order. Random blocks of 4 or 8 will be used. Randomisation sequence will be generated using random.org by an investigator not involved in recruitment. Opened unassigned envelopes will be discarded.

Eligible subjects will be randomly assigned to one of the treatment groups:
First arm: IOL with transcervical Foley catheter without membrane sweeping (standard care)
Second arm: IOL with transcervical Foley catheter with membrane sweeping

Membrane sweeping involves placing a finger into the slightly opened cervix and making a circular, sweeping movement to separate the membranes that surround the baby from the lower uterus, at the same time stretching the cervical opening. If the cervix is closed and does not permit the finger to be inserted, the cervix will be massaged instead.

The Foley catheter is usually inserted digitally (a vaginal speculum can be used if digital insertion is unsuccessful) into the lower womb. The balloon near the tip is then inflated with 60 ml of sterile water. The catheter will be kept for up to 24 hours, after which the balloon will be deflated and catheter removed if not already expelled.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Induction to delivery interval: the duration from foley catheter insertion to delivery time
2. Maternal satisfaction with the delivery process assessed using a 10 cm visual numerical rating scale (scored from 0 to 10) post-delivery in the postnatal ward before discharge

Secondary outcome measures

Maternal outcome measures, obtained from patients medical record at delivery:
1. Mode of delivery such as spontaneous vaginal delivery/Caesarean delivery and its indication and instrumental delivery (forceps and vacuum) and its indication
2. Use of additional method for cervical ripening e.g. prostaglandin use or repeat Foley catheter
3. Spontaneous rupture of membrane or amniotomy
4. Duration of oxytocin use - from time oxytocin started to stopped in hours and minutes
5. Epidural analgesia in labour - whether used or not
6. Estimated delivery blood loss - in ml
7. Fever - temperature in degree Celcius
8. Major harms e.g. severe postpartum haemorrhage (more than or equal 1500 ml), uterine rupture and admission to the intensive care unit

Neonatal outcome measures, obtained from patients medical record at delivery:
1. Apgar score at 1 and 5 minutes
2. Umbilical cord arterial blood pH and base excess
3. Neonatal admission and indication

Overall study start date
01/10/2019

Completion date
31/12/2021

Reason abandoned (if study stopped)
During interim analysis noted that two participants in the intervention arm sustained major harms. Two patients had major harms in swept group where one had uterine rupture and the other one had massive postpartum haemorrhage secondary to cervical tear. The major harms were reported to our trial safety monitoring committee and although judged not to be attributable to trial intervention of adjunctive membrane sweeping, an interim data analysis ordered. The interim analysis indicated that further data accrual was likely to be futile on the primary outcomes and the trial was stopped.

Eligibility

Key inclusion criteria
1. Scheduled for labour induction
2. One previous caesarean section
3. Unripe cervix (Modified Bishop Score ≤ 5)
4. 18 years and above
5. Singleton pregnancy
6. 37 weeks gestation and above
7. Cephalic presentation
8. Reassuring fetal heart rate tracing
9. Absence of significant contraction ≥ 2 in 10 minutes

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
110

Total final enrolment
63

Key exclusion criteria
1. Contraindication to vaginal delivery
2. Known gross fetal anomaly
3. Ruptured membranes
4. Latex allergy
5. Fetal weight clinically estimated to be ≤ 2 kg or ≥ 4kg, then confirmed by ultrasound
6. Preference for repeat Caesarean delivery

Date of first enrolment
18/06/2020

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre Malaysia
Lembah Pantai
Kuala Lumpur
Malaysia
59100

Sponsor information

Organisation
University Malaya Medical Centre

Sponsor details

Lembah Pantai
Kuala Lumpur
Malaysia
59100
+60 (0)3 79494422
ummc@ummc.edu.my

Sponsor type
Hospital/treatment centre

Website
https://www.ummc.edu.my/

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
University Malaya Medical Centre

Results and Publications

Publication and dissemination plan
Study protocol is not published. The researchers plan to publish their trial data as an article in a journal listed in the ISI Web of Science.

Intention to publish date
31/03/2022

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date. Only the investigators will access to the research data. Anonymised (where individuals cannot be identified) trial data may be released to other researchers in the future as permitted by the ethics committee.

IPD sharing plan summary
Data sharing statement to be made available at a later date