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Comparing two methods of stimulating the cervix (neck of the womb) to become ready for childbirth in women who have had one previous Caesarean and are at term in their pregnancy

Submission date
14/11/2018

Recruitment status
No longer recruiting

Registration date
30/11/2018

Overall study status
Completed

Last Edited
27/10/2022

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Labour is induced (started artificially) because earlier delivery is consider to be safer than allowing the pregnancy to continue and occasionally for logistical convenience or maternal preference. Induction of labour in women who have had a Caesarean previously is linked to additional risks, including scar rupture and a higher failure rate resulting in a repeat Caesarean. In selected cases after careful consideration and as requested by women, it is considered a safe process when conducted in a well-resourced setting. Following a successful vaginal birth after Caesarean, mother and baby usually do well and future pregnancies are safer.
The standard method of induction of labour when the cervix (neck of the womb) is not favourable (does not show changes needed for birth to occur) is to use prostaglandin (a signalling chemical naturally found in the body) given into the vagina. Prostaglandin softens the cervix and can also cause contractions, triggering labour. Recently, a new preparation of prostaglandin has been developed. This is applied as a vaginal insert containing a reservoir that slowly releases the drug. This means that the prostaglandin is released more gradually compared to vaginal tablet forms where absorption can be too fast leading to intense contractions. If intense contractions are produced, the insert can be easily removed.
Another method is to use physical pressure to stimulate the cervix, rather than a drug. A Foley catheter is a tube with a balloon at one end. The tube is inserted through the cervix so that the balloon is just inside the womb. The balloon is filled with water and the outside section of the tube is taped to the woman's thigh to apply gentle downward pressure. The balloon pressure on the internal opening of the cervix causes softening and opening (ripening) of the cervix, usually without contractions. The Foley catheter is left for 24 hours unless it gets expelled spontaneously or removed for specific medical reasons. Breaking the waters and an oxytocin drip to produce contractions is more often needed in labour induction with the Foley catheter, compared to when prostaglandins are used.
This study aims to compare use of the Foley catheter and dinoprostone (a type of prostaglandin) delivered as a vaginal insert with a reservoir in women with full-term pregnancies who have previously had one Caesarean section. The two methods of labour induction will be compared in

terms of the time taken from induction to birth and the mother's satisfaction with the birth process.

Who can participate?
Women at over 37 weeks of pregnancy who have had one previous Caesarean and who need to have labour induced.

What does the study involve?
The women will be randomly allocated to the dinoprostone group or the Foley catheter group. In the dinoprostone group, the vaginal insert will be placed in the vagina. It will be removed if there are any problems or if it is still inside the vagina after 24 hours. For women in the Foley catheter group, the catheter will be inserted and the balloon inflated with 60 ml of water.

What are the possible benefits and risks of participating?
Induction of labour after one previous Caesarean can fail to result in vaginal delivery in up to half of women. If it is unsuccessful, then a Caesarean delivery will be needed. There is also a small risk that the previous Caesarean scar can rupture, which would mean that an emergency Caesarean is needed. The vaginal insert can cause uterine (womb) hyperstimulation, which involves very strong and long-lasting contractions or contractions every 2 minutes on average. This can result in problems for the baby or rupture of the womb. If uterine hyperstimulation occurs, the insert must be removed immediately.

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?
July 2018 to December 2019

Who is funding the study?
University Malaya

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
201882-6559

Study information

Scientific Title
Foley catheter compared with dinoprostone sustained-release vaginal insert for labour induction after one previous Caesarean: a randomised trial

Study objectives
Transcervical Foley catheter compared to dinoprostone sustained release vaginal insert will result in a shorter induction to delivery interval and higher patient satisfaction with their birth process.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 05/12/2018:
1. National Medical Research Registry (NMRR), 16/11/2018, ref: 44993
2. University Malaya Medical Centre Medical Research Ethics Committee, 15/11/2018, MREC ID: 201882-6559

Previous ethics approval:
National Medical Research Registry (NMRR), 16/11/2018, ref: 44993

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Induction of labour in term pregnant women with one previous Caesarean delivery

Interventions
Current intervention as of 05/12/2018:
Term women with one previous Caesarean section and unfavourable cervixes undergoing cervical ripening and induction of labour at term in University Malaya Medical Centre, Kuala Lumpur, will be randomised to one of two groups. Women allocated to the Foley group will have a 16G catheter inserted digitally transcervically, or with speculum if digital insertion unsuccessful, according to usual protocol and the balloon will be inflated with 60 ml of water. The Foley catheter will be left for 24 hours if not spontaneously expelled. Women allocated to

dinoprostone sustained-release vaginal insert will have the device inserted as per manufacturer' s instructions. The device will be removed at 24 h if not already expelled spontaneously, at membrane rupture, in the event of uterine hyperstimulation syndrome or if not tolerated.

Previous intervention:
Term women with one previous Caesarean section and unfavourable cervixes undergoing cervical ripening and induction of labour at term in University Malaya Medical Centre, Kuala Lumpur, will be randomised to one of two groups.
Women allocated to the Foley group will have a 16G catheter inserted digitally transcervically according to usual protocol and the balloon will be inflated with 60 ml of water.
Women allocated to dinoprostone sustained release vaginal insert will have the device inserted as per manufacturer's instructions. The device will be removed at 24 h if not already expelled spontaneously, at membrane rupture, in the event of uterine hyperstimulation syndrome or if not tolerated.

Intervention Type
Device

Primary outcome(s)
Current primary outcome measures as of 05/12/2018:
1. Induction to delivery interval assessed using patient medical records and obtained as soon after delivery before discharge
2. Satisfaction of mother with the delivery process using a 10-cm visual analog scale (VAS)

Previous primary outcome measures:
1. Induction to delivery interval assessed using patient medical records.
2. Satisfaction of mother with the delivery process using a 10-cm visual analog scale (VAS)

Key secondary outcome(s))
Current secondary outcome measures as of 05/12/2018:
Maternal outcomes:
1. Maternal satisfaction with their care since allocation to the intervention until removal or expulsion of induction device using a 10-cm VAS – obtained as soon as possible after removal of catheter/device
2. Mode of delivery (obtained after delivery)
3. Switch over to alternate device (obtained after delivery)
4. Spontaneous rupture of membranes (SROM) or amniotomy: date and time (obtained after delivery)
5. Use of oxytocin for induction or intrapartum augmentation (obtained after delivery)
6. Use of epidural analgesia in labour (obtained after delivery)
7. Estimated delivery blood loss (obtained after delivery)
8. Fever ≥38°C (from induction to patient discharge - obtained after discharge)
9. Major complications (intervention to hospital discharge- obtained after discharge)
10. Major complications (scar rupture, blood transfusion, maternal HDU/ICU admission, hysterectomy, re-laparotomy, others)
11. Uterine hyperstimulation syndrome (in the first 24 hours - obtained after delivery) assessed using blinded assessor
12. Terbutaline use for uterine hyperstimulation (obtained after delivery)

Neonatal outcomes:
1. Apgar score at 1 and 5 minutes after birth

2. Arterial cord pH
3. Birth weight
4. Neonatal admission

All outcomes are assessed using patient medical records.

Previous secondary outcome measures:
Maternal outcomes:
1. Maternal satisfaction with their care since allocation to the intervention until removal of induction device using a 10-cm VAS – obtained as soon as possible after removal of catheter /device
2. Mode of delivery (obtained after delivery)
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Neonatal outcomes:
1. Apgar score at 1 and 5 minutes after birth
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All outcomes are assessed using patient medical records.

Completion date
03/06/2019

Eligibility

Key inclusion criteria
1. Scheduled induction of labour
2. One previous Caesarean scar
3. Aged 18 years and above
4. Gestational age of >37 weeks at enrolment
5. Unfavourable cervix (Bishop Score ≤5)
6. Reassuring pre-induction fetal cardiotocography (CTG)
7. Cephalic presentation
8. Singleton pregnancy
9. Intact membranes
10. Absence of significant contraction ≥2 in 10 min

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
78

Key exclusion criteria
Current exclusion criteria as of 05/12/2018:
1. Allergic to latex
2. Allergy or other specific contraindication to dinoprostone
3. Inability to consent
4. Known gross fetal anomaly
5. Grand multiparity (number of pregnancy at or after 22 weeks ≥5)
6. Estimated fetal weight ≤2 kg or ≥4 kg

Previous exclusion criteria:
1. Allergic to latex
2. Allergy or other specific contraindication to dinoprostone
3. Inability to consent
4. Known gross fetal anomaly
5. Parity(number of viable pregnancies) ≥5
6. Estimated fetal weight ≤2 kg or ≥4 kg

Date of first enrolment
12/12/2018

Date of final enrolment
01/06/2019

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya
Lembah pantai

Kuala Lumpur
Malaysia
59100

Sponsor information

Organisation
Obstetrics and Gynaecology department of University Malaya

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
University/education

Funder Name
University Malaya

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/07/2022	27/10/2022	Yes	No
Participant information sheet	version v1	03/07/2018	30/11/2018	No	Yes