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Comparing combined perineal massage and warm compress versus perineal massage during the second stage of labour in nulliparous women

Submission date
27/05/2019

Recruitment status
No longer recruiting

Registration date
12/06/2019

Overall study status
Completed

Last Edited
11/06/2019

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
Vaginal birth can be associated with perineal tears and can be associated with both short and long-term morbidities eg pain, dyspareunia, bleeding and prolong recovery and nulliparous (no previous childbirth) women are at increased risk for perineal tear compared to multiparous (previously given birth) women.
Available techniques to prevent tears during the second stage of labour include perineal massage and warm compress, which have shown a reduction in perineal trauma. Thus this study was done to evaluate the effects of combined perineal massage and warm compression versus perineal massage alone during the active second stage of labour with the need for suturing of perineal trauma at vaginal birth.

Who can participate?
Nulliparous woman presenting in labour with presumed labour with age > 18 years old however the final recruitment only when patient achieve active second stage.

What does the study involve?
Participants will receive usual care during labour until the patient starts to push, then actual intervention will be started. Final eligibility for study entry of those recruited is only fulfilled when the woman in the second stage and about to commence pushing. Only at this point is a sealed envelope assigned and subsequently opened to decide the intervention to be carried out. The intervention will either be perineal massage alone or combined perineal massage with warm compression.

What are the possible benefits and risks of participating?
Both interventions are safely used during the second stage of labour

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?
June 2019 to December 2019

Who is funding the study?
Investigator funded

Who is the main contact?
Suriyanti Ahmad Shukri,
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Combined perineal massage and warm compress versus perineal massage during second stage in nulliparous - randomized control trial

Study objectives
Combine warm compress and perineal massage compared to perineal massage alone in nulliparous woman during second stage should result in less perineal suturing

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/04/2019 Medical research Ethics Committee, University Malaya Medical Centre (Pusat Perkhidmatan Penyelidikan (PPP), Tingkat 2, Institut Pengurusan & Perkhidmatan Penyelidikan (IPPP), University of Malaya, 50603, Kuala Lumpur, Malaysia; 03-79677022 (ext : 2369); umrec@um.edu.my), ref: 201926-7105

Study design
Single centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
Nulliparous women in the second stage of pregnancy

Interventions
This is a randomised control trial involving nulliparous patient at term (>_37 weeks) who are admitted to an antenatal ward or labour ward of UM Hospital. Eligible patients will be identified

using eligibility form and patient information sheet will be provided for those who fulfilled initial eligible criteria. Those who agreed to participate will be asked to provide written consent and will be recruited in this study.
Participants will receive usual care during labour until the patient starts to push, then actual intervention will be started. Final eligibility for study entry of those recruited is only fulfilled when the woman in the second stage and about to commence pushing. Only at this point is sealed number of envelope assigned and subsequently opened for the intervention to be carried out. Intervention will either be perineal massage alone or combine perineal massage with warm compression.
Perineal massage will be performed during contractions. A generous quantity of the KY-jelly will be poured onto fingers and using a gentle, slow massage, with 2 fingers of the gloved hand moving from side to side just inside the patient's vagina. Mild, downward pressure (towards the rectum) is applied with steady, lateral strokes, which last 1 second in each direction. Pressure will be maintained at an intensity at which the woman did not feel any pain.
A warm compress will be applied between contractions. A sterile towel will be soaked in metal container filled with warm water (~50C) and squeezed before being placed gently on the perineum during each uterine contraction. The temperature should range from 38C to 44C during its application. During contractions, the towel should be re-soaked in the water to maintain warmth then reapplied again once the contraction is over. The water in the metal container will be replaced every 15 minutes until delivery or if the temperature dropped below 45C. The water temperature will be checked with a thermometer placed into the container. Total duration of treatment will be during the second stage only.
Patient will be followed up soon after delivery for the outcomes.

Intervention Type
Procedure/Surgery

Primary outcome measure
Requirement for suturing for perineal injury (Episiotomy / spontaneous tears) measured after delivery.

Secondary outcome measures
Maternal outcomes
1. Interval from intervention to delivery
2. Mode of delivery: Vaginal delivery / Operative vaginal delivery / caesarean delivery
3. Indication for operative vaginal delivery/caesarean section
4. Perineal status: Intact, 1st degree, 2nd degree, 3rd degree, 4th degree tear
5. Maternal satisfaction with intervention (rate 1 - 10)
6. Estimated blood loss at delivery

Fetal outcomes
1. Apgar score at 1 min and 5 min
2. Birth weight
3. Arterial cord pH
4. Reason and location of neonatal admission and indication

Overall study start date
07/02/2019

Completion date
07/12/2019

Eligibility

Key inclusion criteria
1 Initial recruitment: Presumed labour / Final recruitment: During active second stage
2 Nulliparous and no previous pregnancy beyond 20 week
3. Age of > 18
4. Gestational age of > 37 weeks at enrolment confirmed by ultrasound greater or less than 20 week
5. Singleton pregnancy
6. Planned vaginal birth
7. Cephalic presentation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
280

Key exclusion criteria
1. Has performed antenatal perineal massage
2. Gross fetal anomaly
3. Gross perineal scarring (e.g. female genital mutilation)
4. Caesarean section (post-randomisation exclusion)

Date of first enrolment
14/06/2019

Date of final enrolment
07/12/2019

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Jalan Universiti
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/12/2020

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other