

Combined massage and warm compress to the perineum during pushing in women delivering for the first time

Submission date 02/01/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/02/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/09/2021	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Perineal injury is very common at a first delivery. Perineal massage or warm compress may reduce very severe perineal injury but studies have shown less clear cut benefit where less severe injury is concerned. There is no reported study where massage and warm compress to the perineum are combined as a single intervention. Combined perineal massage and warm compress during active second stage of labour may protect the perineum compared to the standard care of no intervention to the perineum. The aim of this study is to assess the impact of combined perineal massage and warm compress on sutured perineal injury (including episiotomy and spontaneous tear).

Who can participate?

Women aged over 18 who are giving birth for the first time

What does the study involve?

Participants are randomly allocated to be treated with combined perineal massage and warm compress or usual care (control group). Perineal massage is performed during contractions to minimize contractions. A generous quantity of KY jelly is poured onto the fingers and using a gentle, slow massage with two 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 is maintained at an intensity at which the woman does not feel any pain. Warm compress is applied between contractions. A sterile towel is soaked in a 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 is re-soaked in the water to maintain warmth then applied again. Sutured perineal injuries (including episiotomy or spontaneous perineal tear) are recorded when the baby is delivered.

What are the possible benefits and risks of participating?

Perineal injury might be decreased if these techniques are effective. However, it is also possible that massage and warm compress to the perineum may increase injury. Perineal massage may cause minor abrasion and pain and warm compress may cause discomfort.

Where is the study run from?

University of Malaya Medical Centre (Malaysia)

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

January 2018 to May 2018

Who is funding the study?

University of Malaya Medical Centre (Malaysia)

Who is the main contact?

Dr Goh Yi Pei

Contact information

Type(s)

Scientific

Contact name

Dr Yi Pei Goh

Contact details

University of Malaya Medical Centre
Department of Obstetrics & Gynaecology
Lembah Pantai
Federal Territory of Kuala Lumpur
Malaysia
59100

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2017105-5637

Study information

Scientific Title

Combined massage and warm compress to the perineum during active second stage of labour In nulliparas: a randomised trial

Acronym

MASSCOMP

Study objectives

Combined perineal massage and warm compress during active second stage of labour will decrease the rate of perineal injuries that require suturing.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Ethics Board of University of Malaya Medical Centre, 15/12/2017, ref: 2017105-5637

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Perineal injury, including episiotomy, or spontaneous perineal tears that require suturing

Interventions

Randomisation was done via random.org with both blocks of 4 and blocks of 8 methods. Participants are randomised to be treated with combined perineal massage and warm compress or usual care (control group).

Perineal massage will be performed during contractions to minimize contractions. A generous quantity of KY jelly will be poured onto the 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.

Warm compress will be applied between contractions. A sterile towel will be soaked in a 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. 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.

Control management is without application of combined massage and warm compress to the perineum.

Follow-up is within a day postpartum (the patients will not have a time-framed follow-up).

Intervention Type

Procedure/Surgery

Primary outcome measure

Sutured perineal injury (including episiotomy or spontaneous perineal tear), measured instantly after baby is out

Secondary outcome measures

1. Maternal outcomes, measured instantly after baby is out:
 - 1.1. Interval from intervention to delivery
 - 1.2. Mode of delivery
 - 1.3. Third- and fourth-degree perineal tears
 - 1.4. Maternal satisfaction with intervention, measured using VAS
 - 1.5. Estimated blood loss at delivery
2. Fetal outcomes, measured instantly after baby is out:
 - 2.1. Apgar score at 1 min and 5 min
 - 2.2. Birth weight
 - 2.3. Arterial cord pH
 - 2.4. Neonatal admission and indication

Overall study start date

01/01/2018

Completion date

31/05/2018

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 28/08/2018:

1. Presumed labour (including ruptured membrane)
2. Nulliparous
3. Age > 18
4. Gestational age of > 37 weeks at enrolment
5. Singleton pregnancy
6. Planned vaginal birth
7. Cephalic presentation
8. Reassuring fetal status
9. Not distressed by pain that may impact decision making
10. In active second stage pushing

Previous participant inclusion criteria:

1. Presumed labour (including ruptured membrane)
2. Nulliparous
3. Age > 18
4. Gestational age of > 37 weeks at enrolment
5. Singleton pregnancy
6. Planned vaginal birth
7. Cephalic presentation
8. Reassuring fetal status
9. Not distressed by pain that may impact decision making

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

156

Total final enrolment

156

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

15/01/2018

Date of final enrolment

31/03/2018

Locations

Countries of recruitment

Malaysia

Study participating centre

University of Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
Malaysia
59100

Sponsor information

Organisation

University of Malaya Medical Centre

Sponsor details

Department of Obstetrics & Gynaecology
Lembah Pantai
Federal Territory of Kuala Lumpur
Malaysia
59100

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00vkrxq08>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Department of Obstetrics & Gynaecology, University of Malaya Medical Centre

Results and Publications

Publication and dissemination plan

Planned publication in high-impact peer reviewed journal such as "The Obstetrics & Gynaecology", "BJOG : An International Journal O&G", and "The Urogynaecology Journal", tentatively next year in 2019 if possible.

Intention to publish date

31/05/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Goh Yi Pei. The data is hardcopy type, will become available once the study is done, and will be anonymised.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			01/04/2019	No	Yes
Protocol file			01/04/2019	No	No
Results article		23/01/2021	09/09/2021	Yes	No