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Cold compared with room temperature compress on the perineal repair site following normal vaginal delivery in women who have delivered their first child

Submission date
16/02/2022

Recruitment status
No longer recruiting

Registration date
05/04/2022

Overall study status
Completed

Last Edited
28/12/2023

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
Vaginal delivery offers many benefits such as a rapid recovery process and an early start to the mother-infant relationship especially in primiparous (first birth) women when it is unfortunately often associated with perineal trauma (any damage to the area between the vagina and the anus during the birth of a baby). Cryotherapy (ice pack application) is a non-pharmacological, non-invasive, low-cost therapy, which reduces local tissue temperature. This localised method results in an anti-inflammatory effect that consequently leads to less swelling and pain.

The objective of this proposed study is to evaluate cold versus room temperature compress (placebo) to the perineal repair site on perineal pain in primiparous women.

Who can participate?
All women aged 18 years old and above, in their first pregnancy and planning on vaginal delivery is eligible to participate in this study. The final inclusion criteria will be determined upon completion of perineal repair.

What does the study involve?
The study involved applying either cold or room temperature compress at the perineal repair site at 3 different points of time: immediately post repair, at 4-hour and 8-hour post delivery. The compress will be placed at the perineum for 20minutes each before it is being discarded.

What are the possible benefits and risks of participating?
The purpose of the trial is to evaluate the trial interventions as there is uncertainty about which is better or they may be equivalent. Information obtained from this study will help guide the management of future patients in similar circumstances. Some women may feel the compress to be uncomfortable. As the compress will be placed at the perineum for 20minutes, patient will have difficulty in sitting or walking but they will be provided with proper disposable panties that can support the compress and make them more comfortable without any extra cost. There is no

evidence to show that applying either of this compress will increase risk of perineal wound breakdown.

Where is the study run from?
Department of Obstetrics and Gynaecology, University Malaya Medical Center (Malaysia)

When is the study starting and how long is it expected to run for?
November 2021 to March 2023

Who is funding the study?
Department of Obstetrics and Gynaecology, University Malaya Medical Center (Malaysia)

Who is the main contact?
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MECID number 2021118-10761

Study information

Scientific Title
Cold compared with room temperature compress on the perineal repair site following normal vaginal delivery in primiparous women

Acronym
CROCIP

Study objectives
We hypothesized that women randomised to cold compress compared to controls will have
- lower pain score when mobilizing post-delivery
- lower requirement of oral analgesia
- earlier resumption of vagina intercourse

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/02/2022, Medical Research Ethics Committee of University Malaya Medical Centre (Level 2, Kompleks Pendidikan Sains Kejururawatan, University of Malaya Medical Centre Jalan Professor Ungku Aziz
59100 Kuala Lumpur, Malaysia; +603-7949 3209/2251; ummc-mrec@ummc.edu.my), ref: 2021118-10761

Study design
Interventional single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Supportive care for perineal wound sustained in primiparous women during normal vaginal delivery.

Interventions
Patient who are agreed to participate in this study, will be randomised to:
1. Cold compress (frozen gel pack) - experimental group, or
2. Room temperature compress (using identical gel pack, soft at room temperature) - control group

The allocated pack will be placed against the sutured site of the perineum for 20 min at 3 different time points: immediately after repair, at 4 h after repair, and 8 h after repair.

Analgesia:
Stat dose of 1 g paracetamol po after perineal repair then 1 g paracetamol po qds prn. If breakthrough pain, escalation to 400 mg ibuprofen po qds. Further escalation at care providers' discretion
At discharge 1 g paracetamol po qds prn or if moderate pain, 400 mg ibuprofen po qds prn with 3 days' supply. Further escalation at care providers' discretion

Randomization:
Randomization sequence generated in random blocks of 4 or 8 with within block randomization using https://www.sealedenvelope.com/simple-randomiser/v1/lists by an investigator not involved in recruitment. The randomization sequence is concealed in numbered, sealed opaque envelopes. Randomization is by opening the lowest-numbered envelope remaining for the newest recruit.

Intervention Type
Procedure/Surgery

Primary outcome measure
Perineal pain score measured using a 0-10 numerical rating scale (NRS) at mobilisation, at 12 h after delivery, and 24 h after delivery

Secondary outcome measures
Measured at pre-discharge using patient records:
1. Time to first flatus
2. Time to first satisfactory breastfeeding experience
3. Time to first urination
4. Time to ambulation
5. VNRS: Satisfaction with allocated compress to your perineal repair site (@24 H)
6. Analgesia used

Measured at 14 days after delivery (by telephone):
7. Oral analgesia use for perineal pain
8. VNRS pain score during mobilisation

Measured at 6 weeks after delivery (by telephone):
9. Oral analgesia use for perineal pain
10. VNRS pain score during mobilisation
11. Resumption of vagina intercourse
12. Exclusive breastfeeding
13. Perineal healing (Likert scale)

Overall study start date
05/11/2021

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Nulliparous
2. Planning to have a normal birth
3. ≥18 years old
4. ≥37 weeks gestation
5. Singleton birth
6. Spontaneous vaginal delivery (SVD)
7. Sutured second degree perineal injury: spontaneous or episiotomy
8. Apgar score at 5 minutes ≥9

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
222 (111 in each arm)

Total final enrolment
224

Key exclusion criteria
1. Post-partum haemorrhage (≥1000 ml)
2. Indwelling bladder catheter
3. Admission to high dependency or intensive care
4. Extended or multiple vaginal tears
5. Vulva-vaginal haematoma
6. Cold allergy

Date of first enrolment
09/05/2022

Date of final enrolment
07/02/2023

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Jalan Prof. DiRaja Ungku Aziz
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Sponsor information

Organisation
University Malaya Medical Center

Sponsor details
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Malaya Medical Center

Results and Publications

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

Intention to publish date
31/03/2024

Individual participant data (IPD) sharing plan

Data sharing statement to be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		29/01/2021	21/02/2022	No	Yes
Results article		24/12/2023	28/12/2023	Yes	No