

# 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	Recruitment status	<input checked="" type="checkbox"/> Prospectively registered
16/02/2022	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
05/04/2022	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
28/12/2023	Pregnancy and Childbirth	

## 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?

Dr. Khaliza Kazrin binti Abd Karim, azaareen84@gmail.com

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## Contact information

**Type(s)**

Principal investigator

**Contact name**

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

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

## Study type(s)

Quality of life

## 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(s)

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

## Key secondary outcome(s)

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)

## Completion date

31/03/2023

## Eligibility

### Key inclusion criteria

1. Nulliparous
2. Planning to have a normal birth
3.  $\geq 18$  years old
4.  $\geq 37$  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  $\geq 9$

## Participant type(s)

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**Total final enrolment**

224

**Key exclusion criteria**

1. Post-partum haemorrhage ( $\geq 1000$  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

Kuala Lumpur

Malaysia

59100

## Sponsor information

**Organisation**

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

University Malaya Medical Center

## Results and Publications

### 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?
<a href="#">Results article</a>		24/12/2023	28/12/2023	Yes	No
<a href="#">Participant information sheet</a>		29/01/2021	21/02/2022	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes