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Cold compress on the caesarean wound for pain relief

Submission date	Recruitment status	[X] Prospectively registered
06/05/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/05/2024	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/05/2024	Pregnancy and Childbirth	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Pain from around the wound site is expected after a caesarean section, especially within the first 48 hours of the operation. Appropriate pain management is needed for the patient's comfort and recovery. After caesarean pain relief typically involves different types of painkillers and other non-drug approaches to combine their pain-reducing effects and to minimise the use of opioid drugs. Pain relief efforts should not interfere with the mother's ability to care for her infant, and should have no adverse effects on the baby in breast-feeding women.
Cryotherapy (ice pack application) is a non-drug, non-invasive and low-cost approach to reduce pain after tissue injury. Applying ice or cold compress reduces the skin temperature and changes the perception of pain by reducing the activity of nerves carrying pain signals and pain receptors in the injured area. Cold also causes local veins to constrict thereby relieving pain by reducing bleeding, swelling, and heat. Cold treatment of injury requires an adequate duration of application and correct timing to when the injury occurred to limit further tissue damage. Applying cold compresses to the caesarean wound should reduce swelling and provide temporary numbness, helping women to restore function more quickly and plausibly promote healing.
This study's main aim is to evaluate the repeated application of cold versus room temperature compress to the caesarean wound as part of after-caesarean pain relief.

Who can participate?
Women aged 18 years and over who had a Caesarean section

What does the study involve?
After surgery, participants will be randomly allocated to receive cold (frozen gel pack) or room temperature gel packs. The allocated pack will be placed at the caesarean wound at 6 hours, 12 hours and 18 hours after surgery for 15 minutes at each session. This treatment is additional to the usual after-caesarean painkillers, and additional pain relief can be administered as needed. Pain will be self-scored by the participants just before and just after each application of compress and at 6, 12 and 18 hours after surgery. Another pain score will be assessed at first mobilisation (getting up from bed to move about) a day after surgery. Participants' satisfaction with their allocated wound compress will be recorded. The overall use of painkillers in the hospital will be considered.

Two weeks after the surgery, participants will be telephoned to ask about painkiller use at home and their pain score when moving about.
Six weeks after the surgery participants will again be telephoned to ask about painkiller use at home in the last month (if any), their pain score when moving about using the NRS and their satisfaction with their wound has healed well.

What are the possible benefits and risks of participating?
There may or may not be any benefits to participants; the purpose of the study is to evaluate the interventions as there is uncertainty about which is better or whether the interventions may be equivalent in terms of pain relief and the need for oral painkillers. No major complications are anticipated. Some participants may feel the cold compress to be uncomfortable initially. Wound healing is not expected to be impacted.

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?
August 2023 to April 2025

Who is funding the study?
University Malaya (Malaysia)

Who is the main contact?
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Study website
None

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
20231210-13104

Study information

Scientific Title
Cold compress on the caesarean wound for pain relief: a randomised controlled trial

Acronym
-

Study objectives
It is hypothesised that repeated applications of cold compress to the transverse suprapubic caesarean wound on the day of the operation when pain is most intense will reduce pain assessed the following day at first mobilisation.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/04/2024, University of Malaya Medical Centre Medical Research Ethics Committee (University Malaya Medical Center, Lembah Pantai, 59100, Malaysia; +60 (0)379498473; ummc-mrec@ummc.edu.my), ref: 20231210-13104

Study design
Single-centre interventional parallel group design randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment, Efficacy

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
Caesarean section

Interventions
Participants will be randomised to:
1. Intervention group (cold gel pack)
2. Control group (room temperature gel pack)

The allocated pack will be placed over the entire Caesarean wound at 6, 12 and 18 hours after surgery for 15 minutes during each session.

The randomisation sequence will be generated in random blocks of 4 or 8 with within-block randomisation and in a ratio of 1-to-1 by an investigator who is not involved in recruiting, using online software (https://www.sealedenvelope.com/simple-randomiser/v1/lists). Randomisation sequence is concealed in numbered, sealed opaque envelopes. The random allocation is through opening the lowest numbered envelope remaining for the latest recruit.

Standard after-caesarean pain relief (typically paracetamol 1 g four times daily and celecoxib 200 mg twice daily orally) will be administered and if there is breakthrough pain, escalation to e. g., tramadol 50mg three times a day orally or by injection) at care providers' discretion.

On hospital discharge, paracetamol 1 g four times daily and celecoxib 200 mg twice daily orally will be prescribed as needed for 1 week.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain at first mobilisation (first getting out of bed and moving about, typically on the day after surgery) scored using the 11-point 0-10 numerical rating scale (NRS)

Secondary outcome measures
Measured predischarge:
1. Pain just before and just after each application of compress at 6, 12 and 18 hours after surgery, measured using NRS
2. Maternal satisfaction with allocated compress, measured using Likert scale
3. Pre-discharge analgesia used (type of analgesia and total doses), measured using medical records

Measured at 14 days after delivery (by telephone):
4. Oral analgesia for pain in the last 2 weeks (type of analgesia and total doses)
5. Pain during mobilisation measured using NRS

Measured at 6 weeks after delivery (by telephone):
6. Oral analgesia for pain in the last month (type of analgesia and total doses)
7. Pain during mobilisation measured using NRS
8. Wound has healed well measured using Likert scale

Overall study start date
22/08/2023

Completion date
01/04/2025

Eligibility

Key inclusion criteria
1. Age ≥18 years old
2. Caesarean section
3. Lower transverse suprapubic skin incision
4. Regional (spinal/epidural) anaesthesia
5. BMI <40 kg/m2

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
222

Key exclusion criteria
1. Neonatal admission to intensive care
2. Women who needed intensive or high dependency care after caesarean
3. Does not speak Malay or English

Date of first enrolment
01/06/2024

Date of final enrolment
01/03/2025

Locations

Countries of recruitment
Malaysia

Study participating centre

University Malaya Medical Center
University Malaya Medical Center
Lembah Pantai
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59100

Sponsor information

Organisation
University Malaya Medical Centre

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.ummc.edu.my/#

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
Universiti Malaya

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

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

Intention to publish date
30/09/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Prof. Tan Peng Chiong (pctan@um.edu.my) subject to institutional review board approval.

IPD sharing plan summary
Available on request