

Cold compress on the caesarean wound for pain relief

Submission date 06/05/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/05/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/05/2024	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

1. Dr. Siti Nurhalijah Binti Salam, s2030956@siswa.um.edu.my
2. Prof Dr. Tan Peng Chiong, pctan@um.edu.my
3. Dr Farah Binti Mohd Faiz Gan, farah.faizg@ummc.edu.my
4. Dr Wong Thai Ying, thai.wong@um.edu.my

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Dr Siti Nurhalijah Binti Salam

Contact details

University Malaya Medical Centre

Lembah Pantai

Malaysia

59100

+60 (0)107605274

s2030956@siswa.um.edu.my

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

20231210-13104

Study information

Scientific Title

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

Acronym

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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

Study type(s)

Treatment, Efficacy

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(s)

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)

Key secondary outcome(s)

Measured pre-discharge:

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

45 years

Sex

Female

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

Malaysia

59100

Sponsor information**Organisation**

University Malaya Medical Centre

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, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Malaysia

Results and Publications

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