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Mechanical massage with an electric massage chair on pain relief after a caesarean birth

Submission date
14/06/2024

Recruitment status
No longer recruiting

Registration date
21/06/2024

Overall study status
Completed

Last Edited
21/06/2024

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aim
A caesarean section is the delivery of a baby by an operation through a horizontal cut in the lower portion of the tummy. Globally caesarean births account for 21.2% of births. The caesarean rate is 42.8% in Latin America. The global rate is projected to increase to 28.5% by 2030. In the first 48 hours after a caesarean, moderate to severe pain is often felt. Pain relief after a caesarean is typically a combination of painkilling medicines, anaesthetic injections to numb local nerves and non-drug approaches. With the specific concern of many patients that medicines they consume may have the potential to enter breast milk, a pain control approach that minimises the use of painkillers like massage therapy can have unique appeal as an after-caesarean pain relief method. Manual massage by hand on the patient has been shown to reduce after-caesarean pain. Manual massage is labour-intensive, typically involves a trained therapist and is costly. Recently, mechanical massage with an automated electric massage chair has been shown to reduce pain during labour. Massage using the automated electric massage chair as a pain-relieving method after a caesarean has not been explored. This study aims to evaluate a solitary 30-minute session using an automatic electric chair massage set to provide massage to the posterior body compared to a simple vibration setting after caesarean pain.

Who can participate?
Patients aged 18 to 40 years old delivered by caesarean without complications and who can move about

What does the study involve?
Participants will be assigned at random by a computer to receive full-posterior body mechanical massage or sham vibration using an automated electric massage chair for a solitary 30-minute session. Participants will return to normal ward activities after the 30-minute session. Participants will provide pain scores on movement using a 0-10 numerical rating scale immediately after the massage chair session, and then at 1, 2, 4 and 8 hours after. Eight hours after the massage chair session will be asked to provide a response using a 5-grade Likert scale on whether they agree to recommend their assigned intervention to a friend. Participants will be asked at hospital discharge about bleeding from the wound site and gaping of the wound which will be assessed by the care provider.

The massage will not involve direct contact with the abdomen or the caesarean wound site. These sessions will be on the day after their caesarean, usually in the morning after the participant has started to get out of bed and move about. Participants will be informed that they can stop the massage chair session at any time without having to give a reason and they will be shown the 'stop button' on the massage chair control panel for this purpose.

What are the possible benefits and risks of participating?
Massage using the electric massage chair may have substantial pain-relieving effects and that may allow additional opioid painkillers that are needed by some patients on top of their standard pain medication to be avoided. Electric chair massage of the posterior body may unexpectedly increase pain. It can cause bleeding or slight opening of the wound though there is no direct massage of the tummy or wound area.

Where is this study run from?
Postnatal ward of the University Malaya Medical Centre (UMMC), Malaysia

When is the study starting and how long is it expected to run for?
July 2023 to July 2025

Who is funding the study?
The Department of Obstetrics and Gynaecology at the University of Malaya, Malaysia

Who is the main contact?
1. Dr Nor Atiqah binti Mohd Salleh, atiqah.msalleh@ummc.edu.my, ettysalleh89@gmail.com
2. Prof Tan Peng Chiong, pctan@um.edu.my

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Nor Atiqah Mohd Salleh

Contact details
Department of Obstetrics and Gynaecology
University Malaya
Kuala Lumpur
Malaysia
50603
+60379492059
atiqah.msalleh@ummc.edu.my

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The electric massage chair on post caesarean section pain: a randomised controlled trial

Study objectives
It is hypothesized that a 30-minute session of full-body (posterior aspect) mechanical massage using the electric massage chair the day following a caesarean section reduces pain

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/05/2024, Medical Research Ethics Committee (University Malaya Medical Centre, Jalan Profesor Diraja Ungku Aziz, Seksyen 13, Petaling Jaya, 50603, Malaysia; +60379493209; ummc-mrec@ummc.edu.my), ref: 2024224-13458

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

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Women delivering by caesarean section

Interventions
Participants will be randomised to:
a) Intervention group; a 30-minute full-body (posterior aspect) session of mechanical massage using an automated electric massage chair
OR
b) Placebo group; a 30-minute mechanical vibration session using an identical automated electric massage chair

The session will be initiated on the day following the caesarean section.

Participants are informed that they have the option to stop the massage if they experience discomfort or withdraw without having to explain. They will be shown the ‘stop button’ on the massage chair control panel.

Pain will be scored before the intervention, immediately, and at 1, 2, 4 and 8 hours after the intervention using the 0-10 numerical rating scale (NRS)

The randomisation sequence will be generated in random blocks of 4 or 8 (1 to 1 ratio) using an online generator (https://www.sealedenvelope.com/simple-randomiser/v1/lists) by an investigator not involved in recruitment. Randomisation sequence is concealed within numbered, sealed opaque envelopes. The lowest numbered envelope remaining will be assigned to the latest recruit.

Standard after-caesarean pain relief (typically paracetamol 1 g four times daily and celecoxib 200 mg twice daily orally) escalating e.g, to tramadol 50 mg three times a day (orally or by injection) as needed.

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

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Electric massage chair (uShine, Zero Healthcare, Johor, Malaysia)

Primary outcome(s)
Pain measured using the 0-10 Numerical Rating Scale (NRS) (higher score more pain) scores immediately after the massage chair session, then at 1, 2, 4 and 8 hours later

Key secondary outcome(s))
1. Participants' likelihood to recommend their allocated massage chair treatment to a friend measured using a 5-grade Likert scale as reported by participants 8 hours after the massage chair session
2. Additional opiate analgesia measured using data collected from medical charts from intervention to hospital discharge
3. Intervention to hospital discharge interval measured using data collected from medical charts from intervention to hospital discharge
4. Prescribed analgesics at hospital discharge measured using data collected from medical charts from intervention to hospital discharge
5. Bleeding from the transverse suprapubic incision measured using data collected from medical charts at hospital discharge
6. Separation (≥5mm) of the transverse suprapubic incision site measured using data collected from medical charts at hospital discharge
7. Estimated vaginal bleeding ≥500 ml measured using data collected from medical charts from intervention to hospital discharge
8. Repeated measures analysis of the serial pain scores (from primary outcome 0-10 NRS pain score immediately after the massage chair session, then at 1, 2, 4 and 8 hours later)

Completion date
31/07/2025

Eligibility

Key inclusion criteria

1. No later than 24 hours after Caesarean
2. Able to mobilise
3. Age 18-40 years old
4. Singleton offspring
5. Any parity
6. ≥37 weeks gestation age
7. Lower Segment Caesarean Section
8. Suprapubic transverse skin incision
9. BMI <40 kg/m2
10. Regional anaesthesia only for caesarean

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
40 years

Sex
Female

Key exclusion criteria
1. Complicated caesarean (severe PPH >1500 ml, bowel or bladder injury, balloon tamponade etc)
2. Neonatal complications (admission, structural anomaly etc)
3. Stillbirth
4. ICU/HDU care
5. Ongoing Patient-Controlled Analgesia (PCA) or regional analgesia

Date of first enrolment
01/07/2024

Date of final enrolment
15/07/2025

Locations

Countries of recruitment
Malaysia

Study participating centre

University Malaya Medical Centre
Jalan Profesor Diraja Ungku Aziz, Seksyen 13
Petaling Jaya
Malaysia
50603

Sponsor information

Organisation
University of Malaya

ROR
https://ror.org/00rzspn62

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 analysed during the current study will be available upon request from the investigators, Dr Nor Atiqah binti Mohd Salleh, ettysalleh89@gmail.com, subject to institutional review board approval for board-approved individual patient data metanalysis.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes