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Focused transcutaneous electrical nerve simulation (TENS) to the caesarean wound for pain relief

Submission date 09/12/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 18/12/2025	**Overall study status** Ongoing	
Last Edited 18/12/2025	**Condition category** Signs and Symptoms	

Plain English summary of protocol

Background and study aims
Women who undergo caesarean section often experience moderate to severe pain in the first 48 hours. After a caesarean section, a multimodal analgesic approach is often employed to minimize opioid usage and provide synergistic or additive analgesia. Some studies have shown that transcutaneous electrical nerve simulation (TENS) can help with pain following a caesarean section, but the results vary depending on how it's applied.

In the University Malaya Medical Centre, the standard analgesia for post-caesarean patients is typically paracetamol and celecoxib with opioids as needed. There is sparse data on the impact of focused-TENS applied immediately around the caesarean wound. This study aims to evaluate the application of focused-TENS on localized wound pain.

Who can take part?
Women aged 18 years and above, within 6-24 hours after undergoing caesarean-section under spinal or combined spinal-epidural anaesthesia.

What does the study involve?
The focused-TENS device will deliver TENS through two prongs which are small ball-shaped ended that delivers TENS with a tighter focus and deeper penetration than pad electrodes. These are used to to deliver specific stimulation of 100 Hz frequency and amplitude 5 mA for 15 minutes at 6 fixed points for 5 minutes at each point located 1-2 cm lateral to and 1-2 cm above, along the transverse suprapubic incision similar in principle to multipoint wound infiltration technique with a local anaesthetic. Sham-control with a deactivated identical devices will be similarly applied.

All participants will receive two 15 minutes intervention sessions 4 hours apart. In one group, the session will start with the focused-TENS function activated followed 4 hours later by a second session when the deactivated TENS device will be similarly applied. In the other group,

the order is reversed; first session deactivated-TENS device is applied and second session the activated focused-TENS will be similarly applied. Group assignment of participants will be performed by a computer.

Immediately, 1, 2 and 4 hours after each session, the participants will rate wound pain level when moving about and satisfaction with intervention and blood pressure and pulse rate will be measured with automated device. The standard use of pain killers are permitted as required without any restriction.

What are the possible benefits and risks of participating?
Focused-TENS application may reduce wound pain on moving about. For this short term crossover study, no major benefit is anticipated as focused-TENS will be applied to all participants. Some participants may feel tingling or notice slight redness of the skin at the application site. These effects are expected to be temporary and usually resolve quickly. Participants are instructed that they can withdraw from the study at any time and for any reason including for discomfort.

Where is the study run from?
The study will be conducted at University Malaya Medical Centre (UMMC), Kuala Lumpur, Malaysia.

When is the study starting and how long is it expected to run for?
December 2025 to December 2026.

Who is funding the study?
The University Malaya - Special Research Assistance (Bantuan Khas Penyelidikan)- Early Career Research Grant (BKP-ECRG) 2024, Malaysia.

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University of Malaya Special Research Assistance - Early Career Research Grant (BKP-ECRG) Project No
BKP022-2024-ECRG

Study information

Scientific Title
Focused transcutaneous electrical nerve stimulation to the caesarean wound for pain relief: a blinded randomised sham controlled trial

Acronym
F-TENSPC

Study objectives

To evaluate the impact of applying focused-TENS (Transcutaneous electrical nerve stimulation) around the caesarean section wound on the hypothesis that the intervention will reduce wound pain on moving about in the next 4 hours.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/04/2025, Medical Research Ethics Committee University of Malaya Medical Centre (University of Malaya Medical Centre, LEMBAH PANTAI, 59100, Malaysia; +60 03-79493209/2251; ummc-mrec@ummc.edu.my), ref: 20241223-14516

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Crossover

Purpose
Prevention, Treatment

Study type(s)
Efficacy, Prevention

Health condition(s) or problem(s) studied
Post-caesarean section wound pain on movement

Interventions
This study will employ a blinded randomized, sham-controlled counterbalanced crossover trial design with 4 hours wash out period.

Randomization will be conducted using a computerized sequence generator. The sequence will be generated in random blocks of 4 or 8 (1:1 ratio) via https://www.sealedenvelope.com/simple-randomiser/v1/lists by a co-investigator not involved in trial recruitment. Participants will be assigned to one of two trial arms by opening a numbered, sealed, opaque envelope, with the lowest numbered envelope still available assigned to the latest recruit.
ARM 1 : Focused-TENS followed by SHAM-CONTROL after a 4 hour gap
Or
ARM 2 : SHAM-CONTROL followed by focused-TENS after a 4 hour gap

The intervention will be initiated at least 6 hours after the caesarean section and no later than 24 hours post-caesarean section.

ARM 1: Focused-TENS First: Participants will receive focused-TENS therapy at a frequency of 100 Hz and 5 mA intensity (set at medium pulse width). The focused-TENS device prongs will be applied at 6 fixed points for 5 minutes each, 1-2 cm lateral to wound edge and 1-2 cm above, along the transverse suprapubic incision. After 4 hours wash out, the same focused-TENS device will be used in exactly the same manner with output at sham setting 0 Hz and 0 mA intensity.

ARM 2: Control(Sham) First: Participants will receive sham-controlled TENS therapy with output setting 0 Hz and 0 mA intensity. The focused-TENS device prongs will be applied at 6 fixed points for 5 minutes each, 1-2 cm lateral to wound edge and 1-2 cm above, along the transverse suprapubic incision. After 4 hours wash out, participants will receive focused-TENS therapy at a frequency of 100 Hz and 5 mA intensity (set at medium pulse width).

At the start of both sessions, focused-TENS device prongs set at initial frequency of 10 Hz and 5 mA intensity will be delivered to the dorsum of the hand (at the middle finger metacarpal area) for the participant to appreciate the TENS sensation. The frequency applied will be increased in 10 Hz increments until sensation can be felt. The device prongs will then be applied at the same output setting to the sub-umbilical region to demonstrate that the sensation may or may not be felt at the sub-umbilical region when the TENS device is activated to help sustain the sham process.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Remedius ExStim Pro TENS device

Primary outcome(s)
1. Wound pain on movement following a 15-minute session of focused-TENS or sham-control treatment measured using a 0–10 numerical rating scale at immediately after each session, and at 1, 2, and 4 hours post-treatment (including after counterbalanced crossover)

Key secondary outcome(s))
1. Wound pain on movement following the first 15-minute session of focused-TENS or sham-control treatment only measured using a 0–10 numerical rating scale at immediately after the session, and at 1, 2, and 4 hours post-treatment (including after counterbalanced crossover)

2. Maternal satisfaction measured using a 0-10 numerical rating scale (NRS) at immediately after each session, including after counterbalanced crossover

3. Blood pressure and heart rate measured using an automated blood pressure machine at immediately, 1, 2, and 4 hours after each session, including after counterbalanced crossover

4. Full thickness skin burns to TENS application sites measured using electronic medical records at at the time of discharge

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Elective and emergency lower segment caesarean section (intervention will be initiated at least 6 hours after the caesarean section and no later than 24 hours post-caesarean section)
2. Transverse suprapubic incision
3. Spinal or combined spinal-epidural anaesthesia
4. Age ≥ 18 years
5. Able to communicate in English or Malay
6. Competent to consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Contraindications to TENS (e.g., cardiac pacemaker, skin lesions at electrode sites).
2. Chronic pain conditions requiring ongoing analgesic therapy.
3. Postoperative epidural analgesia
4. Postoperative opioid patient controlled analgesia

Date of first enrolment
31/12/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment

Malaysia

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University of Malaya Medical Centre
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Sponsor information

Organisation
University of Malaya

ROR
https://ror.org/00rzspn62

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Funder type
Not defined

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Universiti Malaya

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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 Dr. Wong Thai Ying (thai.wong@um.edu.my) and/or Prof Tan Peng Chiong (tanpengchiong@yahoo.com) subject to institutional review board approval

IPD sharing plan summary

Available on request