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# A study evaluating a focused electrical nerve stimulation device for pain relief in women after vaginal childbirth

**Submission date**
10/05/2026

**Recruitment status**
Not yet recruiting

**Registration date**
20/05/2026

**Overall study status**
Ongoing

**Last Edited**
19/05/2026

**Condition category**
Pregnancy and Childbirth

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

## Plain English summary of protocol

Background and study aims
Perineal injury is common following vaginal birth and can cause significant discomfort. Transcutaneous electrical nerve stimulation (TENS) is a non-invasive method that uses electrical impulses to relieve pain. This study aims to evaluate how well a novel, focused TENS device reduces early postpartum perineal pain and the need for extra pain medications after perineal repair.

Who can participate?
Women aged 18 years and older who have had a vaginal delivery of a single baby at 37 weeks or more and require perineal repair. Participants must not have had an epidural or have chronic pain conditions.

What does the study involve?
Participants will receive two 10-minute treatment sessions: one with an active TENS device and one with a sham (inactive) device. There will be a 4-hour break between the sessions. Pain levels will be measured at rest and during movement at 5 minutes, 1 hour, 2 hours, and 4 hours after each session.

What are the possible benefits and risks of participating?
A possible benefit is that the focused TENS may help reduce pain when moving about after perineal repair. Possible risks include mild skin irritation or redness at the application site and temporary discomfort from the electrical stimulation.

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

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

Who is funding the study?
Universiti Malaya (Malaysia)

Who is the main contact?
1. Dr Tay Jun Yan, yantay@ummc.edu.my, musiciantay@gmail.com
2. Prof. Dr Tan Peng Chiong, pctan@um.edu.my

# Contact information

### Type(s)
Public, Principal investigator, Scientific

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# Additional identifiers

# Study information

### Scientific Title
Study of a novel focused transcutaneous nerve stimulation device for perineal pain in women undergoing vaginal delivery: a blinded randomised sham controlled trial

### Study objectives
To evaluate the impact of TENS on perineal pain on movement post perineal repair using a 0-10 Numerical Rating Scale (NRS) at four timepoints: a) 5 minutes after completion of intervention, b) 1 hour, c) 2 hours and d) 4 hours.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
approved 25/04/2026, Universiti Malaya Medical Centre-Medical Research Ethics Committee (UMMC-MREC) (Pusat Perubatan Universiti Malaya Lembah Pantai, Kuala Lumpur, 59100, Malaysia; +603 (0)7949 3209; ummc-mrec@ummc.edu.my), ref: 20251210-15989

### Primary study design
Interventional

### Allocation

Randomized controlled trial

## Masking
Blinded (masking used)

## Control
Placebo

## Assignment
Crossover

## Purpose
Treatment

## Study type(s)

## Health condition(s) or problem(s) studied
Perineal pain in women undergoing vaginal delivery

## Interventions
At the beginning of each trial intervention session:
1. Participants will receive a briefing that some electrotherapies do not generate sensations.
2. Participants will receive TENS at a starting intensity of 10 Hz and 5 mA on 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 less sensitive 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.

Application method for TENS device:
The patient will be placed in the left lateral position with bilateral hip flexed to 90 degrees. Ischial tuberosities are then palpated transcutaneously. The surface marking for transcutaneous access is defined as the point immediately medial to the lowest portion of the ischial tuberosity. These points are then marked with an X using an erasable marker. Device prongs will be positioned in the horizontal plane on either side of the X marks perpendicular to the skin surface at a pressure sufficient to indent 50% of the prong bulbs into the soft tissue. Two TENS devices will be used to deliver stimulation simultaneously to the right and left sides, with each site receiving 10 minutes of treatment.

TENS-ON session: The TENS device output setting will be at:
1. Frequency: 10 Hz
2. Pulse width: Medium
3. Amplitude: 10 mA

Control SHAM session: The TENS device output setting will be at:
1. Frequency: 0 Hz
2. Pulse width: Medium
3. Amplitude: 0 mA

Randomization:
Randomization will be to:

1. TENS session followed by SHAM-CONTROL session after a 4-hour gap
or
2. SHAM-CONTROL session followed by TENS session after a 4-hour gap.

SHAM optimization:
1. All participants will be exposed to focused TENS device prongs set at an initial frequency of 10 Hz and 5 mA intensity to be delivered to the dorsum of the hand (at the middle finger metacarpal area) for the participant to appreciate the TENS sensation.
2. 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)
Focused transcutaneous nerve stimulation (TENS) device

### Primary outcome(s)
1. Perineal pain on movement measured using 0 - 10 numerical rating scale (NRS) at 5 minutes after completion of intervention session, 1 hour, 2 hours and 4 hours

### Key secondary outcome(s))
1. Perineal pain score at rest measured using 0 - 10 numerical rating scale (NRS) at 5 minutes after completion of intervention session, 1 hour, 2 hours and 4 hours

### Completion date
31/12/2026

## Eligibility

### Key inclusion criteria
1. Age ≥18 years
2. Singleton pregnancy
3. Term gestation ≥37 weeks
4. Viable pregnancy
5. Cephalic presentation
6. Vaginal delivery
7. Perineal injury requiring repair
8. Initial intervention within 2 hours of completion of repair

### Healthy volunteers allowed
Yes

### Age group
Adult

**Lower age limit**
18 years

**Upper age limit**
47 years

**Sex**
Female

**Total final enrolment**
0

**Key exclusion criteria**
1. Epidural analgesia
2. Chronic pain conditions requiring ongoing analgesic therapy
3. Obstetric anal sphincter injury
4. Contraindications to TENS (e.g., cardiac pacemaker, skin lesions at electrode sites)

**Date of first enrolment**
25/05/2026

**Date of final enrolment**
31/12/2026

# Locations

**Countries of recruitment**
Malaysia

# Sponsor information

**Organisation**
University Malaya Medical Centre

**ROR**
https://ror.org/00vkrxq08

# Funder(s)

**Funder type**

**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

### IPD sharing plan summary
Not expected to be made available

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | | | 11/05/2026 | No | Yes |