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A study on how a novel transcutaneous electrical nerve stimulation (TENS) device reduces pain in patients undergoing gynaecology surgeries

Submission date
15/09/2025

Recruitment status
Recruiting

Registration date
23/09/2025

Overall study status
Ongoing

Last Edited
23/09/2025

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Recent advances in pain management suggest that the optimal treatment requires interfering with multiple targets on pain pathways, known as multimodal analgesia. This approach uses a combination of interventions, each working on a different mechanism of pain to reach maximal pain relief using the lowest effective doses of medications. In addition to medication therapy, there are adjunctive physical and behavioral techniques such as massage therapy, physical therapy, and transcutaneous electrical nerve stimulation (TENS) therapy. According to a study by Baldini G et al, using both pharmacologic and non-pharmacologic interventions can improve pain control, enhance recovery, and increase patient satisfaction. Based on another study by Johnson MI, TENS can be used as an effective adjunct for managing postsurgical pain and to minimize the need for opioid and non-opioid analgesics as part of a multimodal approach to pain. While the basic premise of TENS has remained relatively consistent, advancements in the device technology have led to more sophisticated devices that can target different nerve pathways, offering potential for more effective pain relief. The evidence for the use of these novel TENS devices in controlling pain is still evolving. This study aims to evaluate the analgesic efficacy and patient acceptability of a novel TENS device in the post-operative period.

Who can participate?
Adult patients aged ≥ 18 years old who are undergoing elective or emergency gynaecology surgery (eg: myomectomy, hysterectomy, ovarian/ tubal surgeries) via transverse suprapubic incision under general anaesthesia

What does the study involve?
On Day 1 post-operation, participants will be approached by the researcher to be included in the study. If participants agree to take part, consent will be taken. Participants will then be randomly allocated into one of the two groups: either receiving the active TENS device first, followed by the dummy device or another group receiving the dummy device first, followed by the active TENS device. For example, if a participant is in the group that receives the active TENS first, the

active TENS device will be administered for 15 minutes and the pain score immediately, 1-,2-, and 4- hours post-application will be recorded. Participants will be rested from any device for 4 hours. Following that, the dummy device will be applied for 15 minutes and the pain score immediately, 1-,2- and 4- hours post application will be recorded. Blood pressure and pulse rate post-application of the device will be evaluated. The total opioid consumption after each session will also be recorded. In addition to that, participants' satisfaction with both devices will be recorded. While the study is ongoing, the standard analgesics post-operation will still be administered. The duration of the study is two years.

What are the possible benefits and risks to participants?
There might not be any direct benefit to the participants. However, the outcome of this study will contribute to the future understanding and application of TENS. A TENS device may possibly reduce postoperative pain, thus enhancing recovery and shortening the duration of hospital stay.

A potential risk would be a skin reaction at the site of administration of the TENS device. However, this risk is rare and careful monitoring will be done during the study period.

Where is the study run from?
Obstetrics & Gynaecology Department, University of Malaya.

When is the study starting and how long is it expected to run for?
August 2025 to October 2027

Who is funding the study?
Obstetrics & Gynaecology Department, University of Malaya.

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
RSCH ID-25-06222-ISZ

Study information

Scientific Title
A novel transcutaneous electrical nerve stimulation (TENS) device in patients post gynaecology surgeries: a triple-blind, placebo-controlled counterbalanced crossover trial

Acronym
nTENS study

Study objectives
To evaluate the impact of a novel TENS device on pain in post gynaecology surgery patients through a counterbalanced crossover trial : immediately, 1-, 2- and 4- hours
after novel TENS application using a 0-10 Numerical Rating Scale (11 point NRS).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/08/2025, Medical Research Ethics Committee, University Malaya Medical Centre (University Malaya, Jalan Profesor Ungku Aziz, Lembah Pantai, Kuala Lumpur, 50603, Malaysia; +603 7949 3209 / 2251 / 8473 / 4656; ummc-mrec@ummc.edu.my), ref: 2025715-15344

Study design
Single center interventional triple-blinded, placebo-controlled counterbalanced crossover randomised controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Pain control using novel TENS device in patients post transverse suprapubic gynaecology surgeries

Interventions
Eligible participants will be equally divided into 2 groups through a computer-generated randomisation sequence prepared before the start of the study. The groups will be as follows
Group 1: TENS followed by SHAM-CONTROL after a 4-hour gap
Group 2: SHAM-CONTROL followed by TENS after a 4-hour gap

Participants receiving TENS first: Participants will receive TENS therapy at a frequency of 100 Hz and 5 mA intensity (set at medium pulse width). The TENS device will be applied at 6 fixed points

for 5 minutes each, 1-2cm lateral to the wound edge and 1-2 cm above, covering the transverse suprapubic incision. After a 4-hour washout, the same TENS device will be used in exactly the same manner with output at sham setting 0 Hz and 0 mA intensity.

Participants receiving control(sham) first: Participants will receive sham-control TENS therapy with output setting 0 Hz and 0 mA intensity. The TENS device will be applied at 6 fixed points for 5 minutes each, 1-2 cm lateral to the wound edge and 1-2 cm above, covering the transverse suprapubic incision. After a 4-hour washout, participants will receive TENS therapy at a frequency of 100 Hz and 5 mA intensity (set at medium pulse width).

At the start of both sessions, TENS at a frequency of 100 Hz and 5 mA intensity will be delivered to the subumbilical region, briefly for 30 seconds only to generate a TENS sensation and enhance the sham. If the sensation cannot be tolerated, participation will be stopped.

Participants will still receive standard-of-care analgesics post-gynaecology surgery while undergoing the study.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome(s)
Pain score on movement measured using a 0-10 Numerical Rating Scale (11-point NRS) immediately, 1-, 2- and 4- hours after application of active-TENS vs sham-TENS sessions

Key secondary outcome(s))
1. Variance in serial pain scores between active TENS and sham TENS sessions, measured using data from the repeated measurement of pain scores at one timepoint
2. Pain score on movement will be measured at specified time points following a single 15-minute session of active-TENS or sham-TENS. Comparisons will be made across randomised arms at one timepoint.
3. Pain score on movement, measured using repeated measures ANOVA across all treatment sessions at one timepoint
4. Blood pressure and pulse, measured using standard clinical methods and analysed using repeated measures at 0, 1, 2, and 4 hours after active-TENS or sham-TENS sessions
5. Satisfaction with intervention, measured using an 11-point NRS immediately after each session
6. Opioid consumption, measured using medication usage records after application of active-TENS or sham-TENS device

Completion date
01/10/2027

Eligibility

Key inclusion criteria

1. Age ≥ 18 years old
2. Patients undergoing elective or emergency gynaecology surgery (eg, myomectomy, hysterectomy, ovarian/ tubal surgeries) via transverse suprapubic incision under general anaesthesia
3. Able to communicate in English or Malay
4. Able to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Contraindications to TENS (pacemaker, skin lesions)
2. Chronic pain on regular opioids

Date of first enrolment
29/09/2025

Date of final enrolment
01/10/2027

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Jalan Profesor Ungku Aziz, Lembah Pantai
Kuala Lumpur
Malaysia
50603

Sponsor information

Organisation
University of Malaya

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Medicine, University of Malaya

Alternative Name(s)
Faculty of Medicine - Universiti Malaya, Medicine Department - Faculty of Medicine - Universiti Malaya, medicineumalaya, University of Malaya Faculty of Medicine

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as they are not approved by UM-MREC for sharing. The data can only be assessed by the principal investigator and co-investigators directly involved in the study.

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	version 1.0	15/07/2025	23/09/2025	No	Yes
Protocol file	version 1.0	15/07/2025	23/09/2025	No	No