UNIVERSITY OF MALAYA MEDICAL CENTRE

PARTICIPANT INFORMATION SHEET

Study Title: A Novel Transcutaneous Electrical Nerve Stimulation (TENS) Device in Patients Post Gynaecology Surgeries: A Triple-Blind, Placebo-Controlled Counterbalanced Crossover Trial

Version No: 1

Version Date: 15th July 2025

We would like to invite you to take part in a research study. Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

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1. What is the purpose of this study?

The purpose of the study is to evaluate the impact of a novel TENS device on short term pain when moving about in Day 1 post gynaecology surgery patients.

2.Why is this study important?

This study is important because if it is proven to reduce pain post operation, it may reduce the requirement for analgesia in the form of medication. It may also lead to enhanced recovery and possibly reduce the duration of hospital stay.

3.What type of study is this?

This is a randomized controlled trial which is a type of scientific experiment used to test whether something—like a medicine, treatment, or program—really works.

4.What is the procedure that is being tested? (If applicable)

A novel transcutaneous electrical nerve stimulation (TENS) device, which is a device that sends electrical impulses through the skin, to see the impact on pain.

5.Does the investigatory product contain cultural sensitive ingredients eg: bovine or porcine? (if applicable)

No.

6.Why have I been invited to participate in this study?

Because you have fulfilled the criterias to participate in this study. The criterias are:

a) Age ≥ 18 years old

b) Patients undergoing elective or emergency gynaecology surgery (eg: myomectomy, hysterectomy, ovarian/ tubal surgeries) via transverse suprapubic incision under general anaesthesia

c) Able to communicate in English or Malay

d) Able to provide informed consent

7.Who should not participate in the study?
Anyone with a cardiac pacemaker or with skin lesions at electrode sites.
Anyone with chronic pain conditions requiring ongoing analgesic therapy.

8.Can I refuse to take part in the study?
Yes, you are allowed to not take part in this study as this study is entirely voluntary. If you decide not to participate in the study, it will not affect your standard medical care.

9. What will happen to me if I take part?
On Day 1 post operation, you will be approached by the researcher to be included in the study. If you agree to take part, your consent will be taken. You will then be randomized 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. This will be done on Day 1 post operation. For example, if you are in the group who receives the active TENS first, the active TENS device will be administered to you for 15 minutes and pain score immediately, 1,2 and 4 hours post application will be recorded. You will be rested from any device for 4 hours. Following that, the dummy device will be applied for 15 minutes and pain score immediately, 1,2 and 4 hours post application will be recorded. Your 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, your satisfaction with both the devices will be recorded. While the study is ongoing, your standard analgesics post operation will still be administered.

10.How long will I be involved in this study?
For about 24-48 hours

11.What are the possible disadvantages and risks?
A potential risk would be 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.

12.What are the possible benefits to me?
There might not be any direct benefit to you. However, the outcome of this study will contribute in the future understanding and application of TENS. TENS device may possibly reduce post operative pain, thus enhance recovery and shorten duration of hospital stay.

13.Who will have access to my medical records and research data?
Only the principal investigator, co-investigators directly involved in the study will have access.

14.Will my records/data be kept confidential?
Yes. The hardcopy data will be kept in a secured locker with a lock in the Obstetric and Gynaecology Department of UMMC. The keys to the lock will be kept by the principal investigator.

15.What will happen to any samples I give? (If applicable)
Not applicable.

16.What will happen if I don't want to carry on with the study?
You may opt to withdraw at any point during the study without the need for explanation or clarification, and all data pertaining to you will be discarded. Your standard medical care will not be affected.

17.What if relevant new information about the procedure/ drug/ intervention becomes available? (If applicable)
The Ethics board will be informed and the participants will be made aware.

18.What happens when the research study stops? (If applicable)
Patients will be continued on the standard medical care.

19.What will happen to the results of the research study?
The results will be disseminated through scientific papers and scientific presentation. The anonymity of the participants will be maintained.

20.Will I receive compensation for participating in this study?
No.

21.Who funds this study?
This study is internally funded by Department of Obstetric & Gynaecology, University Malaya Medical Center.

22.Who should I contact if I have additional questions/problems during the course of the study?

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Name of investigator 2:Dr Maherah binti Kamarudin
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Telephone number (Mobile number): 012-7440731

23.Who should I contact if I am unhappy with how the study is being conducted?

Medical Research Ethics Committee
University of Malaya Medical Centre
Telephone number: 03-7949 3209/2251