UNIVERSITY OF MALAYA MEDICAL CENTRE

PARTICIPANT INFORMATION SHEET

Study On a Novel Focused Transcutaneous Nerve Stimulation (TENS) Device For Perineal Pain in Women Post Vaginal delivery. A blinded Randomized Sham Controlled Trial.

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?**

We plan to study how TENS (transcutaneous electrical nerve stimulation) affects patients recovering from perineal tear repair who mainly use non opoid pain reliever like celecoxib and paracetamol

2. **Why this study is important?**

After perineal tear repair, patient usually relies on medications. However, Transcutaneous Electrical Nerve Stimulation (TENS), a non-invasive method that uses electrical impulses to relieve pain, has been effective for pain management after various surgeries, such as heart, gallbladder, and orthopedic surgeries.

Some studies shown that TENS can help with pain following perineal tear repair, but results caries depending on the placement and different type of TENS machine. Our device are more focus on the pudendal nerve which innervates the perineal nerve. This study aims to fill that gap by exploring its effectiveness of TENS for post perineal repaired patients.

3. **What type of study is this?**

This study will use a method where participants are randomly assigned to different treatments in a way that neither the participants nor the researchers know which treatment is being given at any time. Each participant will try both the real treatment and a placebo (inactive treatment) with a 4 hour break in between. This design allows each participant to act as their own comparison, which makes the results more reliable because we eliminate differences between people and reduce potential biases in how participants are chosen or how outcomes are measured.

4. What is the procedure that is being tested?

The impact of TENS on post perineal tear repaired in 5minutes after intervention, 1 hour, 2 hour and 4 hours after applications.

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

Not applicable

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

You fulfil the inclusion criteria of this study

- Woman who has undergone vaginal delivery without epidural analgesia
- Perineal tear or episiotomy repaired within 1 hour
- Singleton pregnancy
- Term gestation≥ 37 weeks
- Age ≥ 18years

7. Who should not participate in this study?

You fulfil the exclusion criteria of this study

- Contraindicaitions to TENS (eg. cardiac pacemaker, skin lesions at electrode sites)
- Chronic pain conditions requiring ongoing analgesic therapy.
- Severe perineal tears beyond second degree

8. Can I refuse to take part in the study?

Yes. Your care will not be affected. You will be given usual post-operative care.

9. What will happen to me if I take part?

You will receive two session of different devices. Each session lasted for 10minutes with 4 hours of wash-out period.

10. How long will I be involved in this study?

Your expected duration of study participation will be from recruitment up to your discharge from hospital.

11. What are the possible disadvantages and risk?

Not applicable.

12. What are the possible benefits for me?

Focused TENS will significantly reduce your post perineal repair pain on moving about.

13. Who will have access to my medical records and research data?

Only the investigators. Annoymised (where individuals cannot be identified) trial data may be released to other researchers in the future as permitted by the Ethics committee.

14. Will my records/date be kept confidential?

Yes.

15. What will happen to any samples I give? (if applicable)

Not applicable

16. What will happened if I don't want to carry on with the study?

You can withdraw from the study at any time without having to provide any reason and your care will also not be affected in any way. Standard care will be provided.

17. What if relevant new information about the procedure/ drug/ intervention becomes available? (If applicable)

Not applicable

18. What happens when the research study stops? (if applicable)

Not applicable

19. What will happen to the results of the research study?

We intend to publish the study's findings in a scientific journal to inform care providers and women.

20. Will I receive compensation for participating in this study?

No payment or compensation will be given.

21. Who funds this study?

Department of Obstetric and gynaecology, UMMC.

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

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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
Email: ummc-mrec@ummc.edu.my

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