PART I — PARTICIPANT INFORMATION SHEET

TENS 2.0 study: transcutaneous electrical nerve stimulation (TENS) as an adjunct to local anaesthesia during transperineal MRI-ultrasound fusion-guided prostate biopsy

Protocol number	TENS2-TPB-RCT-2026
Registry number	ClinicalTrials.gov NCT07578324
Ethics approval	KB/326/2026, 9 July 2026
Study site	Department of Urology, University Clinical Centre, Gdansk, Poland

This is an English translation of the participant information sheet and consent form used at the study site. The Polish version is the authoritative document and is the one signed by participants.

Dear Sir,

you have been scheduled for a transperineal MRI-ultrasound fusion-guided prostate biopsy. In connection with this procedure, we would like to invite you to take part in the TENS 2.0 research study. This document sets out detailed information about the study. Please read all of it carefully before you decide.

Taking part is entirely voluntary. You may decline, or withdraw your consent at any time, without giving a reason and without any consequence for your treatment. A decision not to take part will not affect the quality of the medical care you receive.

If you have any questions, please ask the investigator or the nurse. We are available before you sign the consent form and throughout the study.

1. Why is this study being carried out?

Transperineal prostate biopsy, performed through the skin of the perineum (the area between the scrotum and the anus), is currently the recommended way of taking tissue samples from the prostate. It is safer than the transrectal route because the needle does not pass through the bowel, which greatly reduces the risk of infection.

The procedure is performed under local anaesthesia in an outpatient setting. Some patients nevertheless experience pain while the anaesthetic is being given, particularly during the injection around the prostate gland. We are looking for safe and simple ways to reduce that pain.

Transcutaneous electrical nerve stimulation (TENS) delivers mild electrical impulses through the skin using adhesive electrodes. It is widely used in rehabilitation and pain management and its safety profile is well established. Our earlier study of 84 patients found that TENS used during prostate biopsy may reduce pain. The present study aims to confirm that finding in a larger and better designed trial.

A total of 140 patients will take part at a single centre. Your participation lasts from the day of the biopsy until the follow-up visit approximately 30 days later.

2. What will happen if you agree to take part?

2.1. Random allocation to a group

You will be allocated at random, on a basis similar to the toss of a coin, to one of two groups:

- Active group (TENS plus local anaesthesia): electrodes are applied to the skin of the perineum and the device delivers mild electrical impulses throughout the procedure.
- Control group (sham TENS plus local anaesthesia): electrodes are applied in exactly the same way and the device is switched on in exactly the same way, but no current is delivered.

Important: the intensity of stimulation is set individually and may be clearly noticeable, barely noticeable, or not noticeable at all. Feeling nothing does not mean you are in the control group, and feeling a tingling does not mean you are in the active group. Please do not draw conclusions from what you feel.

Neither you nor the doctor performing the procedure will know which group you have been allocated to. The only person who knows the allocation is the nurse operating the device. She does not assess your pain, does not ask you any questions about how you feel, and collects none of the study data. You may find out your allocation on request once the analysis of the whole study is complete.

2.2. Before the procedure (approximately 10 to 15 minutes)

We will ask you to complete three short questionnaires about anxiety before the procedure and about how you experience pain. The nurse will then explain the pain rating scale and show you the form on which you will record your own ratings.

After that, and before the doctor enters the room, the nurse will apply the electrodes and switch on the device. There will be a brief, gradual increase of intensity to a level that remains comfortable for you; during this the nurse will ask when you first feel anything and whether it is still comfortable.

Please do not comment on any sensation from the device while the doctor is present — neither a tingling nor the absence of one. The doctor must not know which group you are in, because that could affect the result of the study. If a sensation from the device becomes unpleasant during the procedure, please say the single word "device" and the nurse will reduce the intensity or switch the stimulation off.

2.3. During the procedure — how you record your pain ratings

The biopsy itself proceeds exactly as a standard procedure. The only thing that differs is how we collect information about pain.

A clipboard with a form and a thick marker pen will rest on your chest. The form has four rows, one for each stage of the procedure. The doctor will announce the completion of each stage aloud and will name the row, for example: "Block complete — row three." That is your signal to mark one number from 0 to 10 in that row, where 0 means no pain at all and 10 means the worst pain you can imagine.

Nobody will ask you for a pain rating. You record your ratings yourself. This is deliberate: research shows that patients asked directly by the doctor performing the procedure tend to under-report their pain so as not to disappoint him. We want your actual rating, including when it is high.

If at some point you do not manage, or are not able, to mark a rating, this is not a problem and has no consequences — simply move on to the next row at the next signal.

2.4. Immediately after the procedure

On the same form, after the last tissue sample has been taken, you will also mark:

- your level of anxiety on a scale from 0 to 10;

- your satisfaction with the procedure on a scale from 1 to 5;
- which group you think you were in (active / sham / no opinion) and how certain you are. This question serves only to assess how well the blinding worked, and there is no wrong answer.

You then place the completed form in an opaque envelope yourself and seal it. The envelope is labelled only with your study number and carries none of your personal details. The nurse who operates the device has no contact with the form at any point.

2.5. Follow-up visit at approximately 30 days

The 30-day visit is the standard post-biopsy visit that you would have had in any case, and you will receive your histopathology result at it. For the study, we will ask you to complete a short form yourself with a single question: whether you would be willing to undergo the same procedure again in the future (yes / no / unsure).

3. What stays the same?

The biopsy technique, the number of cores taken, the type and dose of local anaesthetic and the entire course of the procedure are identical to a standard outpatient biopsy. The study adds only the TENS electrodes applied before the procedure, the short questionnaires, and the form on which you record your own ratings. No additional injection and no additional procedure is performed. No additional visits are required.

4. Possible benefits

If you are allocated to the active group, you may experience less pain during the procedure. This is not certain, which is precisely why we are conducting the study. If you do not benefit personally, the results may still improve comfort for future patients undergoing prostate biopsy.

5. Possible risks and inconveniences

TENS is a non-invasive, low-cost and safe method used widely in rehabilitation. No device-related complications occurred in our previous study.

Possible mild and transient side effects of TENS include:

- slight redness or irritation of the skin under the electrodes, which resolves on its own once they are removed;
- unpleasant sensations at the stimulation site, such as tingling or twitching, which stop immediately when the intensity is reduced or the device is switched off.

The inconveniences of taking part are chiefly the time spent on the questionnaires before the procedure (approximately 10 to 15 minutes) and the need to mark your ratings on the form during the procedure.

Taking part does not increase the risks of the biopsy itself. The risk of biopsy complications — such as blood in the urine, blood in the semen, perineal pain or temporary difficulty passing urine — is the same as for the standard procedure and was explained to you as part of your consent to the biopsy.

6. Who cannot take part?

You cannot take part if, among other things, you have a cardiac pacemaker or an implantable cardioverter-defibrillator, uncontrolled cardiac arrhythmia, a history of epilepsy, or skin lesions at the electrode sites.

Taking part is also not possible if for any reason you would be unable to mark ratings on the form yourself during the procedure. The doctor will go through all the criteria with you before you are entered into the study.

7. What happens if you decide not to take part, or withdraw your consent?

Declining to take part, or withdrawing consent during the study, has no effect whatsoever on the quality of the treatment you receive. The biopsy will be performed in the standard way regardless of your decision.

If you withdraw your consent, the data collected up to that point remain in the study unless you expressly ask for them to be deleted. We honour a deletion request for all data that have not yet been included in a locked statistical analysis.

8. Confidentiality and personal data protection

The controller of your personal data is the Medical University of Gdansk. Data are processed solely for the purposes of this study, in accordance with the General Data Protection Regulation and applicable law.

You will be given a study number, and all research data are labelled with that number only. The list linking study numbers to personal details is held separately in a locked location and is destroyed after the results are published. Access to the data is restricted to authorised members of the research team and to representatives of the Ethics Committee for monitoring purposes.

In scientific publications, data are presented only in aggregate form, from which individual participants cannot be identified. Anonymised data will be made publicly available after publication in the Open Science Framework repository (osf.io), in line with open science standards. The shared data contain no name, national identification number, date of birth or any other information that would allow you to be identified.

You have the right to access your data, to have them corrected, erased or their processing restricted, and to lodge a complaint with the President of the Personal Data Protection Office.

9. Registration

The study was registered in the international clinical trials registry ClinicalTrials.gov (number NCT07578324) before the first participant was enrolled. The protocol received a favourable opinion from the Ethics Committee of the Medical University of Gdansk (KB/326/2026) before recruitment began. The study is conducted in accordance with the Declaration of Helsinki and the principles of Good Clinical Practice.

Taking part involves no cost to you and no payment for participation.

10. Funding and conflicts of interest

The study has received no external funding and is carried out using the resources of the department. The manufacturer of the TENS device takes no part in the planning, conduct, analysis or publication of the study and has no influence on the results. The investigators declare no conflict of interest.

PART II — INFORMED CONSENT FORM

TENS 2.0 study — transcutaneous electrical nerve stimulation as an adjunct to local anaesthesia during transperineal prostate biopsy

Protocol number	TENS2-TPB-RCT-2026 | ClinicalTrials.gov NCT07578324
Document version	Version 1.0, 10 August 2026
Participant number	_____ (completed by the research team)

Please read the statements below carefully and tick each one that is true for you. Sign only if all the statements are true and no question remains unanswered.

Participant statements

☐ 1. I have received and read the Participant Information Sheet (Part I of this document) concerning the TENS 2.0 study.

☐ 2. I have had the opportunity to ask questions about the study and have received full answers to them.

☐ 3. I understand that participation is voluntary and that I may withdraw my consent at any time, without giving a reason and without consequence for my treatment.

☐ 4. I understand the purpose of the study, the course of the procedure, and the possible benefits and risks of taking part.

☐ 5. I understand that I will be allocated at random to the active or the control group, and that until the analysis is complete neither I nor the doctor performing the procedure will know which group I am in.

☐ 6. I understand that the stimulation may be clearly noticeable, barely noticeable or not noticeable at all, and that feeling nothing does not mean I am in the control group.

☐ 7. I undertake not to comment on sensations from the device while the doctor is present during the procedure.

☐ 8. I consent to completing the questionnaires before the procedure and to recording my own pain, anxiety and satisfaction ratings on the study form during and after the procedure.

☐ 9. I consent to the research team accessing data from my medical records relating to the course of the biopsy and its histopathology result.

☐ 10. I consent to the processing of my personal data for the purposes of this study, in accordance with the GDPR and applicable law.

☐ 11. I understand that anonymised study data, from which I cannot be identified, will be made publicly available in a scientific repository after publication.

☐ 12. I consent to being contacted by telephone or e-mail by the research team in order to complete any missing data or to be informed of the results after publication.

☐ 13. I freely consent to take part in the TENS 2.0 study.

Signatures

Participant	Investigator taking consent
Name (block capitals): _____ Signature: _____ Date and place: _____	Name (block capitals): _____ Signature: _____ Date and place: _____

The investigator confirms that the Participant Information Sheet was provided to the participant, that its content was explained, that all questions were answered, and that adequate time for consideration was given.

A copy of this document (Parts I and II) has been given to the participant. The original is retained in the study file at the Department of Urology.