03.03.2026

Pulsed vs Conventional Radiofrequency of the Ganglion Impar for Coccydynia: A Prospective

Randomized Trial

NCT number: not yet assigned

INFORMED CONSENT FORM
Pulsed vs Conventional Radiofrequency of the Ganglion Impar for Coccydynia: A Prospective Randomized Trial

Participant Number: .....
Participant Name: .....

You are being invited to participate in an observational study titled "Pulsed vs Conventional Radiofrequency of the Ganglion Impar for Coccydynia: A Prospective Randomized Trial" The aim of this study is to compare the effectiveness of two different treatment methods (radiofrequency therapies) in patients with tailbone (coccygeal) pain. Both treatment methods are already routinely used, well-established, and applied worldwide.

This study will include individuals aged 18–80 years with coccygeal pain lasting more than 3 months who have not responded to standard treatments. The coccyx region contains a nerve point (ganglion impar) that plays a role in pain transmission. The treatment is performed as follows: the nerve point is located at the anterior surface of the terminal vertebrae or the first two coccygeal vertebrae. If you agree to undergo radiofrequency treatment for your pain, the procedure will be scheduled.

For patients with coccygeal pain, the procedure is performed in the operating room under fluoroscopy guidance. A needle is inserted, and local anesthetic and steroid are applied for block. To achieve longer-lasting effects, either pulsed or conventional radiofrequency (RF) treatment is applied by pain specialists. Both treatments aim to reduce pain by creating changes in the nerve ganglion that block pain transmission through heat or by producing a lesion at high temperature. Both methods are widely used in Turkey and worldwide, with successful outcomes.

During the procedure, you will receive mild intravenous sedation, and your vital signs (blood pressure, pulse, oxygen saturation) will be continuously monitored. One of the two treatment methods will be randomly applied by the pain specialist. After the procedure, you will be observed for 2 hours before discharge.

To evaluate the effectiveness of the treatment, its impact on daily life, changes in sleep quality, and pain levels, you will be asked questions on the day of the procedure in person, and by phone at 1, 3, 6, and 12 months after the procedure. These data will then be analyzed for research purposes. All information will be kept confidential, and by signing this informed consent form, you grant access to these data for research purposes. Records that could identify you will remain confidential and will not be publicly disclosed; even if the results of the study are published, your identity will remain confidential.

You will be informed in a timely manner if new information arises that may affect your willingness to continue participating in the study. We plan to include approximately 45 patients in each group.

Participation in this study is entirely voluntary. By agreeing to participate, you will help us determine whether one of the two radiofrequency treatments provides superior outcomes in terms of pain, daily activities, sleep quality, and patient satisfaction. You have the right to withdraw from the study at any time without giving a reason. You can refuse to participate or withdraw at any time without any penalty or loss of rights. Choosing not to participate or withdrawing will not affect your medical care in any way. If you have any questions regarding the study, you can contact Dr. Derya Bayram or Dostali Aliyev at +90 543 340 04 30, available 24 hours. Refusing to participate will not affect your treatment.

I have read all the explanations in the Informed Consent Form. Written and verbal explanations regarding the study, including its purpose and procedures, were provided to me by the physician named below. I understand that I am participating voluntarily and that I can withdraw from the study at any time, with or without providing a reason.

I voluntarily agree to participate in this study without any pressure or coercion.

Participant Investigating Physician

Name: ..... Name: .....
Signature: ..... Signature: .....
Date: ..... Date: .....