March 03, 2026
Pulsed vs Conventional Radiofrequency of the Ganglion Impar for Coccydynia: A Prospective Randomized Trial
NCT number: Not yet assigned

Study Protocol

Planned Study Duration:
The study will commence after obtaining ethics committee approval and will continue until the planned number of patients is reached within one year.

Study Type: Prospective Randomized Controlled Trial

Methods and Data Collection

The study will begin after ethics committee approval. Patients presenting to the Pain Medicine (Algology) Clinic with coccydynia who have not benefited from conservative or medical treatments and who are planned to receive ganglion impar pulsed or conventional radiofrequency (RFA) treatment will be included. No new drugs or interventions will be applied; only procedures already performed for patients with existing coccyx pain will be used.

Patients with chronic refractory coccygeal pain who demonstrate at least a 50% reduction in NRS pain score following ganglion impar local anesthetic block will be offered pulsed or conventional RFA. A trans-sacrococcygeal approach will be used for both diagnostic and therapeutic interventions.

Demographic and clinical data including age, sex, body mass index (BMI), pain onset, patient satisfaction, complications, changes in medication use, pain scores, disability, sleep quality, and patient satisfaction scores will be recorded.

Pain Assessment: NRS, a linear scale from 0 (no pain) to 10 (worst imaginable pain), will be used before the procedure and at 1, 3, 6, and 12 months post-procedure.

Disability Assessment: The Oswestry Disability Index (ODI), a self-reported tool assessing functional limitations in daily activities, will be used. It consists of 10 sections scored 0–5. Total scores are multiplied by 2 to give a percentage (0–100%). Categories:

- 0–20%: Minimal disability
- 21–40%: Moderate disability
- 41–60%: Severe disability
- 61–80%: Crippled
- 81–100%: Bed-bound or inactive

Global Perceived Effect (GPE): Measures the patient's perception of their condition compared to baseline. Assessed at 1, 3, 6, and 12 months using a 7-point Likert scale: 1 = Much worse, 2 = Worse, 3 = Slightly worse, 4 = No change, 5 = Slightly better, 6 = Better, 7 = Much better. Scores of 6 or 7 indicate patient satisfaction, recorded at 1, 3, 6, and 12 months post-treatment.

Sleep Quality: Pittsburgh Sleep Quality Index (PSQI) evaluates subjective sleep quality, latency, duration, habitual efficiency, sleep disturbances, sleep medication use, and daytime dysfunction. Each item is scored 0–3; total scores range 0–21. Scores ≤5 indicate good sleep quality; >5 indicates poor sleep quality.

NRS, ODI, PSQI, and GPE scores will be recorded digitally before the procedure and at 1, 3, 6, and 12 months for subsequent analysis.

The questionnaires and surveys to be used in this study are non-cognitive, non-psychological tests with established international validity and can be administered by non-specialist personnel.

Patients included in the study will be randomized into one of two treatment groups using a computer-based random number generation method. The procedure will be performed with the patient in a prone position. A pillow placed under the abdomen will be used to reduce lumbar lordosis. The procedure will be conducted under aseptic conditions. The gluteal region will be prepared using a sterile aseptic technique and draped with sterile surgical cloths.

An aseptic metal marker will be used to localize the sacrococcygeal space, a lateral fluoroscopic projection will be obtained, and the target area will be marked. To anesthetize the area, 2 mL of 2% lidocaine will be injected into the subcutaneous tissue at the upper part of the intergluteal fold. Subsequently, a 22G needle (0.6 × 30 mm) will be positioned with its tip at the ventral aspect of the sacrococcygeal ligament, just anterior to the sacrococcygeal disc. Once the needle is correctly positioned along the sacrococcygeal disc line, 1 mL of radiopaque contrast will be injected. The position of the needle will be confirmed by observing the comma-shaped distribution of the contrast in the retroperitoneal space under lateral fluoroscopy.

Radiofrequency intervention on the ganglion impar will be performed using a radiofrequency generator. A 22G radiofrequency needle (0.7 × 98.6 mm) with a 10 mm active tip will be used. Before the procedure, tissue impedance as well as motor and sensory responses (motor and sensory stimulation) will be checked. Expected tissue impedance is <500 ohms. Sensory paresthesia at <1 V and 50 Hz will be observed around the sacrococcygeal region. Neuroablation will be performed for two cycles of 90 seconds at 80°C. Pulsed radiofrequency (RFA) will be applied for 4 minutes at 42°C following stimulation.

Inclusion Criteria

1. Age 18–80 years.
2. Chronic coccygeal pain lasting longer than 3 months, unresponsive to analgesics, anti-inflammatory drugs, and other conservative treatments.
3. Planned ganglion impar conventional or pulsed RFA.

Exclusion Criteria

1. Incomplete medical records.
2. Loss to follow-up.
3. Technical failure during block procedure.

4. Local infection, bleeding disorders, allergy to contrast agents, or history of spinal surgery.
5. History of malignancy.
6. Refusal to participate.
7. Diagnosed psychological disorders.
8. Individuals unable to communicate or follow instructions.
9. Age <18 or >80 years.

Data Collection and Confidentiality

After obtaining ethics committee approval, patients planned to undergo ganglion impar radiofrequency treatment will be included in the study upon confirmation by the investigators (Derya Bayram and Dostali Aliyev). The investigators will record only the data necessary for the study (such as demographic information including sex, height, weight; pre- and post-procedure pain levels; and questionnaire results) on their personal computer.

During the study, personal identifiers (such as patient name, surname, national ID number, phone number, and address) will not be accessed from the hospital database and will not be recorded electronically or on paper, nor used in the study. Study data (as described above) will be stored solely on the personal computers of the investigators (Derya Bayram and Dostali Aliyev) and will not be shared electronically or in any other form (e.g., via email, internet, or other means). Only the investigators will have access to these data. All study data on the investigators' computers will be permanently deleted six months after the completion of the study.

NRS, ODI, PSQI, and GPE scores will be recorded digitally before the procedure and at 1, 3, 6, and 12 months for subsequent analysis.

Sample Size

The sample size to be included in the study was calculated using the G*Power 3.1 software. The primary endpoint of the study is the 12-month Numerical Rating Scale (NRS) pain score. (Test family: t-tests; Statistical test: Means – difference between two independent means, two groups). The significance level (α) was set at 0.05 and the statistical power (1−β) at 80%. Based on an effect size of d = 0.8, approximately 26 patients per group were required. Considering the 12-month follow-up period and a potential 15–20% drop-out rate, the target sample size was set at approximately 45 patients per group, for a total of 90 patients.

Statistical Methods:
Data will be analyzed using IBM SPSS Statistics 26. Continuous data will be reported as mean ± SD and min–max; categorical data as number and percentage (n%). Normality will be tested using the One-Sample Kolmogorov-Smirnov test. Parametric tests will be used for normally distributed variables; non-parametric tests otherwise. NRS, GPE, ODI, and PSQI comparisons

between groups will use the Mann-Whitney U test. Repeated measures will be analyzed using Friedman and Wilcoxon tests. Correlations between NRS, ODI, GPE, PSQI, and demographics will be evaluated using Spearman's rank correlation. $p < 0.05$ will be considered statistically significant.