

Interventional symptomatic treatment of knee osteoarthritis using ablation of the nerves surrounding the knee joint

Submission date 07/06/2026	Recruitment status Recruiting	☐ Prospectively registered ☒ Protocol
Registration date 15/06/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 15/06/2026	Condition category Musculoskeletal Diseases	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Osteoarthritis (OA) is a degenerative joint disease involving the cartilage and many of its surrounding tissues. While total knee arthroplasty is an effective treatment option for end-stage knee arthritis and persistent severe pain, the relatively slow progression of the disease allows for a stepwise algorithmic approach in management using non-surgical treatment options. Through the wide array of non-surgical treatment options, cooled radiofrequency ablation has been proposed.

Radiofrequency ablation (RFA) is the process of thermal nerve degradation through a probe providing radiofrequency energy. Cooled radiofrequency ablation (CRFA) uses a water supply system to internally cool the RFA probe. While the internally cooled probes operate at a temperature of 60°C, the temperature of the surrounding tissues reaches 80°C, thus providing a larger lesion around the probe. The procedure aims to disrupt the transmission of pain signals from the osteoarthritic knee via the genicular nerves.

The primary objective of this study is to evaluate the efficacy of CRFA at 1-, 3-, and 6-months post-intervention in patients with painful knee OA using a numerical rating pain scale (NRPS).

Who can participate?

What does the study involve?

Three groups of patients would be investigated: group CRFA4 = classical anatomical targets (4 nerves), group CRFA6 = revised and classical anatomical targets (6 nerves) and group CRFA8 = Additional (IPBSN & RFN), Revised and Classical anatomical targets (8 nerves).

The secondary objectives are the comparison of safety and tolerability of the interventions, as well as the patient's clinical outcome questionnaires at 3- and 6-months post-intervention.

What are the possible benefits and risks of participating?

The benefits are immediate relief of pain, avoidance of a complex surgery especially in older

patients with medical comorbidities. The risks of participating are few, as it is a minimally invasive technique on an outpatient basis without serious complications.

Where is the study run from?
University of Patras, Greece.

When is the study starting and how long is it expected to run for?
September 2025 to June 2027

Who is funding the study?
The Patras University and Patras University Hospital, Greece.

Who is the main contact?
Prof Andreas Panagopoulos, andpan21@gmail.com, anpanagop@med.upatras.gr

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Prof Andreas Panagopoulos

Contact details
Patras University Hospital
Patras
Greece
26504
+306944363624
anpanagop@med.upatras.gr

Additional identifiers

Study information

Scientific Title
Classic vs New Anatomical Targets for Cooled Radiofrequency Ablation of the Genicular Nerves in the Symptomatic Management of Knee Osteoarthritis: A Prospective, Randomized, Double-Blind Clinical Trial

Acronym
CRFAKA

Study objectives
The primary objective of our proposed randomized trial is to evaluate the efficacy of CRFA at 1-3- and 6-months post-intervention in patients with painful KOA using the Numerical Rating Pain Scale (NRPS). Three groups of patients would be investigated: group CRFA4 = classical anatomical targets (4 nerves), group CRFA6 = revised and classical anatomical targets (6 nerves) and group CRFA8 = Additional (IPBSN & RFN), Revised and Classical anatomical targets (8 nerves). The secondary objectives are the comparison of safety and tolerability of the interventions, as

well as the patient's clinical outcome at 3- and 6-months post-intervention, using the Knee Injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS-JR), the Oxford Knee Score (OKS), the SF-12 and the Forgotten Joint Score (FJS).

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 10/05/2021, Bioethics Committee of Patras University (University Campus, building A, pATRAS, 26504, Greece; +30 2610 997245; uprescom@upatras.gr), ref: 11846/05/10/2021

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Active

Assignment

Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Moderated osteoarthritis of the knee joint

Interventions

Patients will be placed on the radiolucent table at the Department of Interventional Radiology in a supine position with a bolster under the knee to produce 30° of flexion; this position flattens the suprapatellar joint space, thus minimizing needle trespass, and also allows for an unobstructed lateral view of the knee. The treated knee will be draped and sterilized in a standard manner. Patients will be continuously monitored and administered conscious sedation (1–2 mg IV midazolam and/or fentanyl 25–100 mcg IV) and supplemental oxygen. Fluoroscopic images will be obtained to align the femur in an anteroposterior (AP) view to target the genicular nerves at locations above the femoral condyles and for the IMG, a greater caudal tilt of the fluoroscope will be obtained to square off the tibial plateau for an appropriate AP view. A sealed and opaque envelope will be brought to the operating theatre, dictating the group of each patient. The location of the nerves (SLGN, SMGN, IMG, MRGN, IPBSN and RFN) will be identified using fluoroscopy, according to previously described methods. Two to 3 ml of 1% lidocaine is used to anesthetize the skin and subcutaneous tissues before cannula insertion at each target site under fluoroscopic guidance. Thereafter, a 75 mm, 17-gauge introducer needle will be placed to ablate the targeted nerves. One milliliter of 2% lidocaine will be injected through the introducer needles to anesthetize the area before ablation. After placement of the

introducer needle, an 18-gauge, internally cooled 4-mm active tip RFA electrode (Coolief, Halyard Health, Alpharetta, GA, USA) will be placed into the introducer needle, and the positioning is checked again using fluoroscopy. The introducer is connected to the COOLIEF* Cooled RF Advanced Generator that allows staggered start, stop and adjustment of 4 independent channels. The cooled radiofrequency ablation (CRFA) probes will be advanced, and ablation will be performed with lesion settings at 60 °C (80–90 °C adjacent tissue temperature) for 2.5 min. As mentioned before, this type of ablation creates a spherical lesion at the tip of the probe. Cooled RF electrodes include a thermocouple at the active electrode tip to provide a temperature-controlled lesion formation. This involves water-cooling of the active electrode tip during the duration of the process without tissue charring at the electrode tip; this mechanism doubles the lesion radius and increases the lesion volume by 5 times.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Pain associated with knee OA measured using the Numerical Rating Pain Scale (NRPS) at 1, 3, and 6-month post-intervention

Key secondary outcome(s)

1. Safety and tolerability of the interventions, and patient's clinical outcome measured using the Knee Injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS-JR), the Oxford Knee Score (OKS), the SF-12 and the Forgotten Joint Score (FJS) at 1-, 3- and 6-months post-intervention

Completion date

30/06/2027

Eligibility

Key inclusion criteria

Patients of either sex will participate in the clinical trial as long as they have:

1. The NICE clinical criteria of primary knee OA for one or both knees:
 - 1.1. Age >45 years
 - 1.2. Activity-related joint pain
 - 1.3. No morning joint stiffness or morning stiffness that lasts no longer than 30 minutes
2. Radiological confirmation of knee arthritis (grade ≥ 2) according to the Kellgren and Lawrence classification
3. Chronic knee pain for a minimum duration of 6 months
4. Pain intensity ≥ 4 on the (NRPS)
5. Lack of pain relief from conventional therapy, including nonsteroidal anti-inflammatory drugs (NSAIDs), opioids, muscle relaxants, oral steroids, physical therapy, and intra-articular injection therapy.
6. The ability to communicate in Greek

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

45 Years

Upper age limit

90 Years

Sex

All

Total final enrolment

75

Key exclusion criteria

1. inflammatory or post-traumatic knee arthritis
2. Patients who have received CRFA treatment in the past
3. Injection of hyaluronic acid or corticosteroid within the previous 3 months
4. Significant structural deformities affecting locomotion and knee function aside from osteoarthritis and which might cause chronic knee pain
5. Body mass index ≥ 40 kg/m²
6. Uncontrolled serious disease (cancer, diabetes, end-stage heart disease etc)
7. Unstable psychiatric illness
8. Coagulopathy or bleeding disorders
9. Active systemic or local infection

Date of first enrolment

01/09/2025

Date of final enrolment

31/12/2026

Locations**Countries of recruitment**

Greece

Study participating centre

University Hospitals of Patras

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Patras

Greece

26504

Sponsor information**Organisation**

University of Patras

ROR

<https://ror.org/017wvtq80>

Funder(s)

Funder type

Funder Name

University of Patras

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Greece

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during the current study will be published as a supplement to the subsequent results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			08/06/2026	No	No
Participant information sheet			08/06/2026	No	Yes
Protocol file			08/06/2026	No	No