Cover Page for ClinicalTrials.gov

Document: Study protocol

Study Title: Percutaneous Transcatheter Embolization of Knee Arteries in Osteoarthrosis

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Percutaneous transcatheter embolization of knee arteries in osteoarthritis

Study, protocol and methodology

1. Introduction and aim of the study

Knee osteoarthritis (gonarthrosis) is a chronic degenerative disease characterized by the gradual loss of articular cartilage, remodeling of the subchondral bone and the development of chronic pain, which significantly affects the quality of life of patients. Current treatment options include conservative therapy, pharmacological treatment, injections of hyaluronic acid, corticosteroids and, in advanced cases, total knee arthroplasty. However, in some patients, pain persists even after TEP, or they are not suitable for TEP. In recent years, targeted endovascular embolization of synovial arteries supplying the knee joint has emerged as a promising method.

The aim of this prospective, interventional clinical study is to evaluate the efficacy and safety of percutaneous microcatheter embolization of knee arteries using a temporary embolization material (Imipenem/Cilastatin) in patients with advanced knee osteoarthritis or chronic pain after total knee arthroplasty.

2. Overview of current knowledge

Endovascular embolization of the knee joint is a newly developing minimally invasive method that aims to reduce hypervascularization and inflammatory activity in the area of the synovial membrane. Studies published mainly in Japan, South Korea and the USA in 2019–2024 have shown a significant reduction in pain and improvement in the functional capacity of the joint in patients with gonarthrosis grade II–IV according to Kellgren-Lawrence. The mechanism of action is based on the reduction of pathological neovascularization and the interruption of afferent nociceptive pathways.

3. Hypothesis and scientific questions

Hypothesis: Percutaneous embolization of knee arteries using a microcatheter is a safe and effective method that leads to pain reduction and improved knee joint function in patients with grade II–IV osteoarthritis or chronic pain after TEP.

Scientific questions:

• What is the extent of pain relief after the procedure as measured by VAS?
• Is there an improvement in the functional capacity of the knee joint according to WOMAC and KOOS scores?
• What is the technical success rate of the intervention and the incidence of complications associated with the procedure?

4. Study design and plan

This is a single-center, prospective, open-label pilot study with a planned number of 20 patients. Patients will be followed for 24 months. Check-ups will be performed after 1, 3, 6, 12 and 24 months.

5. Inclusion and exclusion criteria

Inclusion criteria:

• age 40–80 years
• clinically and radiologically confirmed gonarthrosis grade II–IV according to Kellgren-Lawrence
• patients with pain unresponsive to conservative treatment or with persistent pain after arthroplasty
• patients unsuitable for arthroplasty of the knee joint

Exclusion criteria:

• active infection
• coagulopathy
• peripheral arterial disease
• allergy to contrast medium
• renal insufficiency
• history of fibromyalgia
• patient's refusal

6. Description of the intervention

The procedure will be performed in the angiography room under local anesthesia. After puncture of the common femoral artery, a microcatheter will be inserted into the arterial branches supplying the knee joint and DSA will be performed. The target lesions have a typical "blush" appearance representing pathological neovascularization. Embolization will be performed by applying a suspension of Imipenem/Cilastatin dissolved in saline with a contrast agent until the flow in the target branch is stopped.

7. Evaluation of efficacy and safety

The primary endpoint is the change in pain intensity according to the visual analogue scale (VAS) between baseline and 6 months after the procedure. Secondary endpoints include change in WOMAC score, KOOS

score, reduction in analgesic use, improvement in range of motion and quality of life. Safety will be assessed by monitoring complications (hematoma, pseudoaneurysm, infection, allergic reaction, paresthesia, transient skin blanching in the embolization area).

8. Monitored parameters and evaluation methods

• VAS – visual analogue scale of pain
• WOMAC score – functional assessment of the knee joint
• KOOS score – pain, symptoms, daily activities, sports and recreation, quality of life
• Use of analgesics (mg/day)
• Clinical examination (swelling, range of motion, stability)
• Imaging methods: knee X-ray, or MRI as indicated

9. Statistical analysis

Data will be processed using descriptive statistics. To compare parameters before and after the procedure, paired t-test or Wilcoxon test will be used depending on the data distribution. Significance will be determined at the $p < 0.05$ level.

10. Ethical aspects

The study will be conducted in accordance with the Declaration of Helsinki and the applicable laws of the Czech Republic. Each participant will provide written informed consent. The ethics committee will be informed about the progress of the study. Patients may withdraw at any time without giving a reason and without impact on further treatment.

11. Protection of personal data

All data will be anonymized and stored in accordance with EU Regulation 2016/679 (GDPR). Only the study investigators will have access to the identifying data. After the study is completed, the personal data will be destroyed.

12. Schedule and organization

Planned duration: January 2026 – December 2027. Place of implementation: Radiology and Orthopedic Clinic of Masaryk Hospital in Ústí nad Labem, oz, Regional Health Company Research team: MUDr. Patrik Matras (principal investigator), MUDr. Pavol Vigláš, MUDr. Vojtěch Smolka, MUDr. Tomáš Novotný, PhD. MBA.

13. Conclusion

This protocol describes the design of a prospective clinical trial aimed at evaluating the effectiveness and safety of percutaneous knee artery embolization in osteoarthritis. We assume that the results will contribute to expanding treatment options for patients with gonarthrosis and chronic pain after TEP and will enable the introduction of a minimally invasive method into routine clinical practice.