Cover Page for ClinicalTrials.gov

Document: Informed Consent Form Official

Study Title: Percutaneous Transcatheter Embolization of Knee Arteries in Arthrosis

Document Date: December 29, 2025

Patient information

on **Percutaneous Transcatheter Embolization of Knee Arteries in Arthrosis** (hereinafter referred to as the "project")

Dear Sir/Madam,

We would like to invite you to participate in a project dealing with embolization of knee arteries in knee joint osteoarthritis. Before you decide to participate, it is important that you understand why this project is being conducted and what it involves. Please pay attention to the following information. Please ask if anything in the text is unclear or if you require more information.
After reading and clarifying any questions, we will ask you to decide whether or not you agree to participate. If you decide to participate in the project, you will express your consent by signing at the end of this document.

What is the purpose of this project: The aim of the project is to evaluate the efficacy and safety of percutaneous embolization of the knee arteries in the treatment of chronic knee pain in patients with advanced osteoarthritis who do not respond to conservative treatment, or in patients with pain after total endoprosthesis.

What are the benefits of the project: The project may improve patients' quality of life, reduce pain, improve joint function, and reduce the need for analgesics.

Why were you selected for the study*?* Because you suffer from grade II-IV Kellgren-Lawrence knee osteoarthritis or chronic pain after total joint replacement, and previous treatment has not provided sufficient pain relief.

Do you have to participate in the project?
Participation in the project is entirely voluntary. Even if you decide to participate, you can withdraw from the project at any time without giving a reason.

Consequences of withdrawing from the project
The decision to participate or refuse to participate in this project will not affect the future healthcare provided to you in any way. Your personal data used for the project up to that point will remain stored in the project, but will no longer be updated or processed.

What participation in the project means for you:
If you decide to participate in the project, you will undergo a minimally invasive procedure – percutaneous embolization of the knee arteries. The procedure is performed in the angiography room under local anesthesia. Follow-up examinations will be performed after 1, 3, 6, 12, and 24 months.

What personal data will we collect and process, for what purpose, to whom will we transfer it, and for how long will the data be processed?

a) Data scope: first name, last name, date of birth, birth number, medical records, including medical history, diagnosis, results of clinical and laboratory examinations, course of treatment, and imaging documentation
For the purposes of: - conducting and evaluating clinical studies
- maintaining a register of patients undergoing this type of treatment in the Czech Republic

To whom we will transfer it: only to members of the research team – MUDr. Patrik Matras (principal investigator), MUDr. Pavol Vigláš, MUDr. Vojtěch Smolka, MUDr. Tomáš Novotný, Ph.D., MBA.

For how long: 5 years after the end of the project

How we will process your data
The data will be processed electronically and in paper form, always in a pseudonymized form, i.e., under a unique identification code. The identification key is kept only by your attending physician. Other entities work exclusively with pseudonymized data.

In what form will we process and transfer your data
We will process and transfer your data for the above purposes only in pseudonymized form, i.e., all data will be provided only under a unique code or identifier (so-called pseudonymization).

Who will process your data and how
Your data will first be pseudonymized by your attending physician and entered into the registry in this form. The pseudonymization key is stored exclusively with the attending physician. The cooperating entities will then use this pseudonymized data to fulfill the project.

Confidentiality
All organizations and persons involved in the processing of the data will be contractually obliged to ensure that all persons authorized to process the data are bound by a contractual confidentiality obligation or are subject to a corresponding statutory confidentiality obligation.

Information about your rights:

- You have the right to request access to your personal data, its correction or deletion, or restriction of processing.

- You have the right to object to the processing of your personal data.

- You have the right to lodge a complaint with a supervisory authority if you believe that the processing of personal data is in breach of the law. Contact details of the supervisory authority: Office for Personal Data Protection, Pplk. Sochora 27, 170 00 Prague 7, electronic mailroom:posta@uoou.cz .

- You have the right to withdraw this consent to data processing by sending a notification to the email address patrik.matras@kzcr.eu, to your attending physician, or in another form to the contact details for personal data processing. Krajská zdravotní a.s. has appointed Ing. Michal Mert, MBA, MSc., LL.M. **as its data protection officer**. The contact details of this officer are: Sedmidomky 456/2, Prague 10 - Michle, 101 00, Czech Republic, e-mail: dpo@kzcr.eu.

Contact for further information
If you have any further questions, please do not hesitate to contact the following persons: MUDr. Patrik Matras, email:patrik.matras@kzcr.eu and MUDr. Pavol Vigláš, email: pavol.viglas@kzcr.eu. If you agree to participate in the described project, please sign the informed consent form. One copy of this document will remain with your attending physician and one copy will be given to you.

Thank you for taking the time to read this information.

Informed consent to participate in the *Percutaneous Transcatheter Embolization of Knee Arteries in Osteoarthritis* project and consent to the provision, processing, and storage of personal data for the purposes of the project

I hereby declare that I have carefully read the Patient Information above, for which I was given sufficient time. I had the opportunity to ask questions about this project, and all my questions were answered sufficiently, and at the same time I received enough information about the project to be able to decide whether or not to enter the project. I understand that my participation is voluntary and I know that I have the option to withdraw from the project at any time, even without giving a reason. I have also been informed of my rights.

Based on the above**, I agree** to participate in this project and to the processing of my personal data, which I confirm with my signature. I give my consent voluntarily and to the extent specified in the Patient Information.

I grant this consent to:
1) The controller and processor Krajská zdravotní a.s. – Masarykova nemocnice v Ústí nad Labem o.z., Sociální péče 3316/12A, 400 11 Ústí nad Labem.

I hereby instruct the personal data controller Krajská zdravotní, a.s. to provide the above personal data to the following recipients:
1) members of the research team for the period specified in the Patient Information

for the duration of this consent.

Name of patient: .....

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

Name of physician: .....

Signature ..... Date:

Workplace:.....