Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Effect of Genicular Artery Embolization for the Treatment of Knee Pain Secondary to Osteoarthritis in patients refferd to Urmia Imam Khomeini Hospital

Protocol summary

Study aim

Determining the effect of genicular artery embolization in the treatment of pain secondary to knee arthritis

Design

This will be a single-center, unblinded, single-group clinical trial that will evaluate the reduction of knee pain symptoms in patients with knee osteoarthritis after geniculate artery embolization compared to the contralateral knee.

Settings and conduct

This clinical trial will be conducted on 23 patients with osteoarthritis in both knees at Imam Khomeini Hospital in Urmia. The study will be open-label, and the patients will be informed about the intervention and the specific knee being treated.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Age between 45 and 75 years with symptoms of knee pain in both knees. 2. Radiographic findings in both knees with a grade of 2 to 4 based on the Kellgren-Lawrence classification 3. VAS score above 50/100 for both knees. 4. Pain resistant to medical and supportive treatments for a duration of 3 months. 5. All patients must agree not to use any oral or injectable painkillers and supplements during the study period and, if necessary, take medications according to the study protocol. Exclusion Criteria: 1. Pregnancy. 2. GFR < 60 ml/min/1.73m². 3. Sensitivity to contrast agents. 4. BMI > 40 kg/m². 5. History of joint injection in the last 3 months. 6. Joint infection or inflammatory joint disease. 7. Life expectancy of less than 2.5 years. 8. Platelet count less than 30,000 per microliter. 9. Allergy to iodinated contrast agents. 10. Presence of joint prosthesis or history of joint surgery. 11. Kellgren-Lawrence grade 4 findings. 12. Absence of palpable pulse.

Intervention groups

Patients are subjected to embolization of the geniculate artery of one knee and the condition of the intervened knee is compared with the opposite knee.

Main outcome variables

Pain score; functional performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240615062136N1**
Registration date: **2024-10-18, 1403/07/27**
Registration timing: **registered_while_recruiting**

Last update: **2024-10-18, 1403/07/27**
Update count: **0**

Registration date

2024-10-18, 1403/07/27

Registrant information

Name

Arian Haghtalab

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-05, 1403/06/15

Expected recruitment end date

2024-12-05, 1403/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Genicular Artery Embolization for the Treatment of Knee Pain Secondary to Osteoarthritis in patients refferd to Urmia Imam Khomeini Hospital

Public title

Investigating the Effect of Genicular Artery Embolization for the Treatment of Knee Osteoarthritis Pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 45 and 75 years with symptoms of knee pain in both knees Radiographic findings in both knees with a grade of 2 to 4 based on the Kellgren-Lawrence classification VAS score above 50/100 for both knees Pain resistant to medical and supportive treatments for a duration of 3 months All patients must agree not to use any oral or injectable painkillers and supplements during the study period and, if necessary, take medications according to the study protocol

Exclusion criteria:

Pregnancy GFR < 60 ml/min/1.73m² Sensitivity to contrast agents BMI > 40 kg/m² History of joint injection in the last 3 months Joint infection or inflammatory joint disease Life expectancy of less than 2.5 years Platelet count less than 30,000 per microliter Allergy to iodinated contrast agents Presence of joint prosthesis or history of joint surgery Absence of palpable pulse

Age

From **45 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **23**

More than 1 sample in each individual

Number of samples in each individual: **2**

Patient's Knee

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Imam Khomeini Hospital, Urmia University of Medical Sciences

Street address

Imam Khomeini Hospital, Ershad St., Modarres Blvd.

City

Urmia

Province

West Azarbaijan

Postal code

5715789397

Approval date

2024-07-10, 1403/04/20

Ethics committee reference number

IR.UMSU.HIMAM.REC.1403.054

Health conditions studied

1

Description of health condition studied

Osteoarthritis of Knee

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Pain Score

Timepoint

Before, after one month and three months of the intervention

Method of measurement

Visual Analogue Scale

2

Description

Functional Performance

Timepoint

Before, after one month and three months of the intervention

Method of measurement

The Western Ontario and McMaster Universities Osteoarthritis Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who undergo embolization of the genicular artery of one knee. Both knees of each patient are examined, and the knees are randomly assigned to either intervention or control (23 intervention knees and 23 control knees). A 2.8-F microcatheter is selectively used to target the genicular arteries in the knee area with the most severe pain. Digital subtraction angiography (DSA) is performed at a low frame rate (1-2 frames per second) and continues until "tumor blush" is observed in delayed images. Embolization is then performed using 150-250 micron embolic particles. The embolization technique involves mixing the particles in a solution with 10 ml of contrast medium. After mixing the liquid to create a homogeneous solution, 2 ml is injected. The injection is performed with repeated digital subtraction angiography until tumor blush is no longer observed in delayed images. This process is repeated for each genicular artery feeding the knee area with the most severe pain. A repeat angiography via the femoral artery is performed to eliminate any untreated branches. All individuals receive an antibiotic dose before the procedure and for 5 days afterward. Pain medication is prescribed for the post-embolization period (up to 1 week after the procedure) in all groups. Patients are discharged 6 hours after the procedure. An initial follow-up phone call is made the day after the procedure to assess acute events. Subsequent follow-ups are conducted one month after the procedure. All post-operative data is collected and recorded by study staff.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Ima Khomeini Hospital of Urmia
Full name of responsible person
Parisa Noorabadi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Oroumia University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Parisa Noorabadi
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Associate Professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available