Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessing the effectiveness of Trans-catheter Arterial Micro Embolization (TAME) in patients with severe knee osteoarthritis

Protocol summary

Study aim

The main objectives: Evaluation of the effectiveness of TAME treatment in the patients with severe osteoarthritis of the knee Sub-objectives: determination of mean age, gender and BMI distribution, duration of pain, Kellgren and Lawrence classification (KL), pain intensity (before, one, three and 6 months after treatment) in patients with sever knee osteoarthritis referred for TAME treatment

Design

single-blinded before-after clinical trial on 30 patients

Settings and conduct

After local anesthesia and injection of 2000 units of heparin, angiography will be performed in the genicular, patellar and tibial arteries. The patient will be asked about the location of the pain, and if the site of pain matches a site with abnormal staining, embolization will be done using 2 units of polyvinyl alcohol 355/500,following pain severity will be measured based on VAS from 1-10. The data analyzer is blind to clinical outcome.

Participants/Inclusion and exclusion criteria

inclusion:severe osteoarthritis (KL grade 4) without age and sex limitation . Receive at least 3 months of outpatient treatments including NSAIDs, opioids and intra-articular hyaluronic acid injection and physiotherapy (muscle strengthening) without improvement. surgery contraindication due to medical conditions (i.e cardiovascular disease). exclusion: malignancy, local infection, rheumatoid arthritis, history of knee surgery, advanced atherosclerosis.

Intervention groups

before-after clinical trial on the effect of TAME on patients with severe knee joint osteoarthritis

Main outcome variables

Studies have not shown major complications such as osteonecrosis, septic arthritis, or cases lead to hospitalization. Minor complications: Erythema at the site of embolization (most common 11%), hematoma at the puncture site (10%), paresthesia (1%) and fever (about 0.5%)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140712018457N5**
Registration date: **2022-05-10, 1401/02/20**
Registration timing: **prospective**

Last update: **2022-05-10, 1401/02/20**
Update count: **0**

Registration date

2022-05-10, 1401/02/20

Registrant information

Name

Hossein Ghanaati

Name of organization / entity

Advanced Diagnostic and Interventional Radiology Research Center (ADIR), Tehran University of Medica

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1516

Email address

ghenaati@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effectiveness of Trans-catheter Arterial Micro Embolization (TAME) in patients with severe knee osteoarthritis

Public title

Effectiveness of Trans-catheter Arterial Micro Embolization (TAME) in severe knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with severe osteoarthritis on examination (KL grade 4) without age and sex restrictions referred by orthopedist Receiving outpatient treatment including NSAIDs, Opioids and intra-articular Hyaluronic Acid injections and physiotherapy for at least 3 months without significant improvement Contraindication for surgery regarding medical conditions such as cardiovascular diseases

Exclusion criteria:

Malignancy, local infection, Rheumatoid Arthritis History of knee surgery Advanced (high grade) Atherosclerosis

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the data coding, the data analyzer is unaware of the patient's final clinical outcome and angiography (single blinded)

Placebo

Not used

Assignment

Single

Other design features

Dear Head of Clinical Trial Registration, considering we are waiting to receive the IRCT code before starting the study, we will start data gathering from late may 2022, best regards.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Imam Khomeini Hospital Complex

Street address

Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2022-02-05, 1400/11/16

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.414

Health conditions studied

1

Description of health condition studied

Patients with severe knee Osteoarthritis (Kellgren and Lawrence classification / KL grade 4)

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Knee pain

Timepoint

Before the intervention and at one ,three and 6 months following procedure

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with severe knee osteoarthritis (KL grade 4)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital Complex

Full name of responsible person
Hossein Ghanaati

Street address
Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6658 1579

Email
ghanaati@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Hossein Ghanaanti

Street address
Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6658 1579

Email
ghanaati@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source
1

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
Tehran University of Medical Sciences

Full name of responsible person
Mahsa Alborzi

Position
Research assistant, General practitioner

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
66581579 021

Email
mahsaalborzi94@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mahsa Alborzi

Position
General practitioner, Research assistant

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
Keshavarz blvd

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6658 1579

Email
mahsaalborzi94@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Hossein Ghanaati

Position
Professor of radiology

Latest degree
Subspecialist
Other areas of specialty/work
Radiology
Street address
Kevarz blvd
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6658 1579
Email
ghanaati@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
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