

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 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 severe 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

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+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 Ghanaati

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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**

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

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### 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**

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**Other areas of specialty/work**

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### 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

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**Province**

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**Phone**

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**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