# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

11 Sep 2026

# Evaluation of the Effectiveness and Safety of Imipenem/Cilastatin Transarterial Embolization for Reducing Pain and Improving Shoulder Function in Patients with Treatment-Resistant Adhesive Capsulitis: A Single-Arm Pilot Clinical Trial

## Protocol summary


**Study aim**
To evaluate the effectiveness and safety of transarterial embolization using imipenem/cilastatin in patients with treatment-resistant adhesive capsulitis.

**Design**
Single-arm, pre–post pilot clinical trial without randomization or a control group, with blinded outcome assessment, conducted in 17 patients. The study is designed as a pilot trial, and no clinical trial phase is applicable.

**Settings and conduct**
Eligible patients will undergo transarterial embolization using imipenem/cilastatin at the Radiology Department of Imam Khomeini Hospital and will be followed for 6 months to assess the effectiveness and safety of the intervention.

**Participants/Inclusion and exclusion criteria**
Patients with treatment-resistant adhesive capsulitis. Inclusion Criteria: Age 18–75 years. Clinical diagnosis of adhesive capsulitis with limited active and passive shoulder motion. Refractory to ≥3 months of standard conservative treatment (physiotherapy, NSAIDs, and ≤1 intra-articular corticosteroid injection). <30% improvement in VAS or <20° improvement in shoulder flexion or abduction. Imaging excluding full-thickness rotator cuff tear, advanced osteoarthritis, or avascular necrosis. Exclusion Criteria: Active infection. Uncorrectable coagulation disorder. Severe allergy to contrast media or beta-lactam antibiotics. Pregnancy or breastfeeding. Severe vascular disease precluding safe catheterization. Presence of other shoulder disorders, including fracture, inflammatory arthritis, or malignancy. Inability to provide informed consent or comply with follow-up.

**Intervention groups**
Single intervention group: All participants will undergo transarterial embolization using imipenem/cilastatin.

**Main outcome variables**
VAS Constant–Murley ROM


## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20250715066507N2**
Registration date: **2026-08-20, 1405/05/29**
Registration timing: **prospective**

Last update: **2026-08-20, 1405/05/29**
Update count: **0**

**Registration date**
2026-08-20, 1405/05/29


**Registrant information**

**Name**
Hamed Ghorani

**Name of organization / entity**

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Iran (Islamic Republic of)

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+98 21 2261 8012

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**Recruitment status**
**recruiting**

**Funding source**

**Expected recruitment start date**
2026-09-03, 1405/06/12

**Expected recruitment end date**
2027-08-03, 1406/05/12

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Evaluation of the Effectiveness and Safety of Imipenem/Cilastatin Transarterial Embolization for Reducing Pain and Improving Shoulder Function in Patients with Treatment-Resistant Adhesive Capsulitis: A Single-Arm Pilot Clinical Trial

**Public title**
Evaluation of the Efficacy and Safety of Arterial Embolization Using Imipenem/Cilastatin in the Management of Treatment-Resistant Adhesive Capsulitis of the Shoulder: A Single-Arm Pilot Trial
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age between 18 and 75 Clinical diagnosis of adhesive capsulitis with limitation of both active and passive shoulder range of motion, particularly external rotation. Failure to respond to at least 3 months of standard conservative treatment, including structured physiotherapy, nonsteroidal anti-inflammatory drugs (NSAIDs), and a maximum of one intra-articular corticosteroid injection.Less than 30% improvement in pain severity (VAS) or less than 20° improvement in shoulder flexion or abduction range of motion compared with baseline Imaging performed to exclude other shoulder pathologies, such as full-thickness rotator cuff tear, advanced osteoarthritis, or avascular necrosis.
**Exclusion criteria:**
Active infection. Uncorrectable coagulation disorder Severe allergy to contrast media or beta-lactam antibiotics. Pregnancy or breastfeeding. Severe vascular disease precluding safe catheterization. Presence of other shoulder disorders, including fracture, inflammatory arthritis, or malignancy Inability to provide informed consent or comply with follow-up.
**Age**
From **18 years** old to **75 years** old
**Gender**
Both

**Phase**
0
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **17**
**Randomization (investigator's opinion)**
N/A
**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**
Research Ethics Committee of the Center of Elites and Talents of the Armed Forces
**Street address**
No. 182, Shahid Beheshti School of Governance, corner of Shohada Street, Ghaem Magham Farahani Street, Shahid Beheshti Street, Tehran 1586755414, Iran.
**City**
Tehran
**Province**
Tehran
**Postal code**
1586755414
**Approval date**
2026-08-02, 1405/05/11
**Ethics committee reference number**
IR.SBMU.TEB.POLICE.REC.1405.017

## Health conditions studied

### 1

**Description of health condition studied**
Treatment-resistant adhesive capsulitis of the shoulder
**ICD-10 code**
M75.0
**ICD-10 code description**
Adhesive capsulitis of shoulder

## Primary outcomes

### 1

**Description**
Shoulder pain severity
**Timepoint**
Baseline (pre-intervention), 1 month, 3 months, and 6 months post-intervention.
**Method of measurement**
Pain severity will be assessed using the Visual Analog Scale (VAS).

### 2

**Description**
Shoulder function
**Timepoint**
Baseline (pre-intervention), 1 month, 3 months, and 6

months post-intervention.

**Method of measurement**

Shoulder function will be assessed using the Constant–Murley Score (CMS).

**3**

**Description**

Shoulder range of motion (ROM)

**Timepoint**

Baseline (pre-intervention), 1 month, 3 months, and 6 months post-intervention.

**Method of measurement**

Shoulder range of motion (flexion, abduction, and external rotation) will be measured using a goniometer.

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group: All eligible participants will undergo transarterial embolization using imipenem/cilastatin. The procedure will be performed by an interventional radiologist to embolize the pathological arterial branches supplying the shoulder joint capsule.

**Category**

Treatment - Surgery

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Radiology Department, Imam Khomeini Hospital

**Full name of responsible person**

Hamed Ghorani

**Street address**

Department of Radiology, Imam Khomeini Hospital Complex, Dr. Gharib Street, Keshavarz Boulevard, Tehran, Iran.

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Center of Elites and Top Talents, Law Enforcement Command of the Islamic Republic of Iran (FARAJA)

**Full name of responsible person**

سیروس افشار

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Shahid Khalilzadeh Military Base, Shahid Sayyad Shirazi Expressway, south of Resalat Square, Tehran, Iran.

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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**

Center of Elites and Top Talents, Law Enforcement Command of the Islamic Republic of Iran (FARAJA)

**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**

Tehran University of Medical Sciences

**Full name of responsible person**

Hamed Ghorani

**Position**

Radiologist

**Latest degree**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Koyar Hiwa Raouf

**Position**

Researcher

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Radiology

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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The shared dataset will include de-identified participant data, demographic and clinical characteristics, imaging findings, procedural details of transarterial embolization, and clinical outcomes including pain severity (VAS), shoulder function (Constant–Murley Score), and shoulder range of motion measured at baseline and at 1, 3, and 6 months after the intervention. No personally identifiable information will be shared.

**When the data will become available and for how long**

De-identified data will be available upon reasonable request after publication of the study results for a period of five years.

**To whom data/document is available**

Qualified researchers, research institutions, and scientific journals may access the de-identified dataset upon reasonable request and approval by the principal investigator.

**Under which criteria data/document could be used**

The de-identified data may be used for scientific research, educational purposes, systematic reviews, and meta-analyses following approval by the principal investigator. All data must be used in accordance with research ethics and participant confidentiality requirements.

**From where data/document is obtainable**

Requests should be directed to the Principal Investigator (Dr. Hamed Ghorani) through Imam Khomeini Hospital Complex.

**What processes are involved for a request to access data/document**

Applicants must submit a written request describing the intended use of the data. The request will be reviewed by the principal investigator for scientific and ethical appropriateness. Upon approval, the de-identified dataset will be shared.

**Comments**