Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Country
Iran (Islamic Republic of)

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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

Street address

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

Specialist

Other areas of specialty/work

Radiology

Street address

No. 8, 4th Floor, South Abdollah Shokrabi Alley, Naz Alley, Heydari Street, Daneshgar, South Attari Moghaddam, Khaghani Street (Zargandeh), Shariati Street, Tehran, Iran.

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Person responsible for updating data

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Koyar Hiwa Raouf

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Latest degree

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Other areas of specialty/work

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Email

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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