

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Evaluation of response to calcitonin treatment in patients with frozen shoulder in selected hospitals of Islamic Azad University of Medical Sciences, Tehran in 2022

#### Protocol summary

##### Study aim

Determination of response to treatment with calcitonin in patients with frozen shoulder

##### Design

This research has two groups of common treatment and combined treatment, which is based on the random selection of samples based on the inclusion criteria and is done by lottery. The sample size of the study is 64 people and the clinical trial phase.

##### Settings and conduct

The samples are divided into two separate groups, the common treatment group receives current common treatments, but the combined treatment group receives intranasal calcitonin spray of 200 units in addition to common treatments, the results are compared, the place of study Orthopedic clinic is a selected hospital of Tehran Islamic Azad University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with a clinical diagnosis of frozen shoulder based on symptoms including limitation in all active and passive movements of the shoulder joint in all directions along with relatively severe pain, reduced range of motion of the shoulder and definitive confirmation of the diagnosis with the help of MRI of the shoulder joint  
Conditions of non-entry: The patient's shoulder pain is accompanied by other causes other than the diagnosis of frozen shoulder, such as strain, dislocation, separation, tendonitis, bursitis, rotator cuff tendon rupture, fracture, etc.

##### Intervention groups

Common treatment group: Aspirin administration, non-steroidal anti-inflammatory drugs, intra-articular injection of steroid and physiotherapy. Combined treatment group: 200 units intranasal calcitonin spray is prescribed along with the common treatment.

##### Main outcome variables

Improvement of pain and range of motion in patients

with frozen shoulder after receiving intranasal calcitonin spray

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220523054971N1**

Registration date: **2023-04-03, 1402/01/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-04-03, 1402/01/14**

Update count: **0**

##### Registration date

2023-04-03, 1402/01/14

##### Registrant information

##### Name

Pedram Nourmandipoor

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2219 4993

##### Email address

pedramnourmandipoor7536@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-19, 1400/09/28

##### Expected recruitment end date

2023-08-22, 1402/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of response to calcitonin treatment in patients with frozen shoulder in selected hospitals of Islamic Azad University of Medical Sciences, Tehran in 2022

**Public title**  
Effect of calcitonin in frozen shoulder treatment

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients with a clinical diagnosis of frozen shoulder  
Patients symptoms including limitation in all active and passive movements of the shoulder joint in all directions  
Patients with relatively severe pain  
Patients with reduction in the range of motion of the shoulder  
Definite confirmation of the diagnosis with the help of MRI of the shoulder joint  
**Exclusion criteria:**

**Age**  
No age limit

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  

- Participant

**Sample size**  
Target sample size: **64**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Sampling is based on a simple random sampling method and based on lottery, cards are prepared according to the sample volume and the desired number is recorded on each card, the cards are placed in a box, then the cards are mixed, and they get out of the box by accident and one after the other until the capacity of both groups is completed.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
After determining the samples of the combined treatment group and obtaining informed consent from them, calcitonin nasal spray is added to the common treatment of this group of patients.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran Islamic Azad University of Medical Sciences

##### Street address

Headquarters Building of Tehran Islamic Azad University of Medical Sciences, Corner of Gol Yakh St., Aineh Blvd., Amir Pabarja St., Gholhak Blvd., Doctor Shariati Ave., Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1949635881

#### Approval date

2022-05-16, 1401/02/26

#### Ethics committee reference number

IR.IAU.TMU.REC.1401.012

## Health conditions studied

### 1

#### Description of health condition studied

Frozen shoulder

#### ICD-10 code

M75.00

#### ICD-10 code description

Adhesive capsulitis of unspecified shoulder

## Primary outcomes

### 1

#### Description

Pain changes with visual analogue scale(VAS)

#### Timepoint

6 weeks after receiving calcitonin nasal spray

#### Method of measurement

Visual analogue scale

### 2

#### Description

Changes in the range of motion with the angle scale in degrees

#### Timepoint

6 weeks after receiving calcitonin nasal spray

#### Method of measurement

Degrees of angle

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients receiving calcitonin nasal spray in addition to common treatments; In this group of patients, intranasal calcitonin spray of 200 units is prescribed along with current common treatments such as aspirin, ibuprofen, intra-articular injection of steroids and physical therapy; the effect of this treatment method is checked from the time of administration to 6 weeks later in the form of face-to-face interview or phone call and compared with the results of the control group.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Patients receiving common treatments; This group of patients receives current common treatments such as aspirin, ibuprofen, intra-articular injection of steroids and physiotherapy, and the results of the intervention group are compared with the results of this group.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amiralmomenin Javadieh Hospital

##### Full name of responsible person

Dr Naser Rahbar

##### Street address

In front of Sardar jangal Park, Shirmohammadi St., Naziabad, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1811694784

##### Phone

+98 21 5534 6550

##### Fax

+98 21 5534 6301

##### Email

amhos@iautmu.ac.ir

##### Web page address

<https://tms.iau.ir>

### 2

#### Recruitment center

##### Name of recruitment center

Bu Ali Hospital

##### Full name of responsible person

Dr Alireza Teimouri

#### Street address

At the beginning of Damavand St., Imam Hossein Sq., Tehran, Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

17117

#### Phone

+98 21 3334 8036

#### Fax

+98 21 3378 6182

#### Email

booli.hospital96@gmail.com

#### Web page address

<https://tms.iau.ir/bouali>

### 3

#### Recruitment center

##### Name of recruitment center

Farhikhtegan Hospital

##### Full name of responsible person

Dr Hamidreza Gholamrezaiee

##### Street address

In front of the Central Organization Islamic Azad University, University Sq., The End of Sattari North Highway, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1477899679

##### Phone

+98 21 4486 7262

##### Fax

+98 21 4484 5171

##### Email

farhikhteganhospital@gmail.com

##### Web page address

<https://tms.iau.ir/farhikhtegan>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Dr Masoud Parsania

##### Street address

Tehran Islamic Azad University Of Medical Sciences, Danesh Dead-end., Attari Moghaddam St., Shahid Khaghani St., Shariati St., Tehran, Iran

##### City

Tehran

##### Province

Tehran

**Postal code**

1916893813

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+98 21 2200 6660

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**Email**

iau-tmuj@yahoo.com

**Web page address**

https://tms.iau.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Islamic Azad University

**Proportion provided by this source**

100

**Public or private sector**

Private

**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**

Islamic Azad University

**Full name of responsible person**

Dr Afshin Farhadi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

**Street address**

Amiralmomenin Hospital, In front of Sardar Jangal Park, Shirmohammadi St., Naziabad, Tehran, Iran

**City**

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**Province**

Tehran

**Postal code**

1811694784

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afshinfarhadi53@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr Afshin Farhadi

**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

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**City**

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**Province**

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**Postal code**

1811694784

**Phone**

+98 21 5534 6550

**Email**

afshinfarhadi53@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr Afshin Farhadi

**Position**

Associate professor

**Latest degree**

Specialist

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**City**

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**Province**

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**Postal code**

1811694784

**Phone**

+98 21 5534 6550

**Email**

afshinfarhadi53@gmail.com

**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**

All data can be shared after de-identifying study participants.

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

Access to the data starts 6 months after the publication of the thesis.

**To whom data/document is available**

General doctors and orthopedic specialists

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

The data can be used for further research to achieve the definite effect of the treatment method, to access the data, you should talk to the scientific officer of the research.

**From where data/document is obtainable**

Visit in person to Dr. Afshin farhadi at the address of Tehran, Naziabad, Shirmohammadi St., In front of Sardar Jangal Park, Amiralmomenin Javadieh Hospital, Building No. 3, Orthopedic Clinic

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

Visit in person to obtain permission from the scientific research officer

**Comments**