

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

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Web page address

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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

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booali.hospital96@gmail.com

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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

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Email

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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

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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
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

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Dr Afshin Farhadi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Latest degree
Specialist

Other areas of specialty/work
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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