

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of Calcitonin effects on shoulder adhesive capsulitis

Protocol summary

Study aim

This study is conducted to evaluate the effect of nasal calcitonin on pain and range of motion improvement in patients with shoulder adhesive capsulitis.

Design

A randomized, blinded clinical trial with two parallel groups of 100 patients.

Settings and conduct

This study is done in Kashani hospital , Isfahan, iran.

Participants/Inclusion and exclusion criteria

Inclusion criterion: ١. Patients diagnosed with adhesive capsulitis(Diagnostic criterion: 1. Shoulder pain and stiffness for at least 4 weeks 2. Severe shoulder pain that restricts daily activities 3. Nocturnal pain 4. Limitation in active and passive range of motion ٢. Patients in first stage of disease(Progressive pain and limitation in range of motion from past 3 months) ٣. Patient agreement to enter the trial ٤. 30 to 60 years old patients Exclusion criterion: 1. Patients with history of trauma, surgery, corticosteroid injection or any previous injury to the shoulder. 2. Patients who had received other treatments including surgical or nonsurgical treatments prior to entering the trial.

Intervention groups

Intervention group: This group receives nasal calcitonin spray. It should be used with dosage of one puff daily for 8 weeks. Control group: This group does not receive calcitonin spray

Main outcome variables

Pain ; Range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210223050470N1**

Registration date: **2021-05-22, 1400/03/01**

Registration timing: **prospective**

Last update: **2021-05-22, 1400/03/01**

Update count: **0**

Registration date

2021-05-22, 1400/03/01

Registrant information

Name

Shakiba Dehghani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 8644

Email address

shakibadehghanii@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Calcitonin effects on shoulder adhesive capsulitis

Public title

Calcitonin in shoulder adhesive capsulitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with adhesive capsulitis (Diagnostic criterion: 1. Shoulder pain and stiffness for at least 4

weeks 2. Severe shoulder pain that restricts daily activities 3. Nocturnal pain 4. Limitation in active and passive range of motion Patients in first stage of disease(Progressive pain and limitation in range of motion from past 3 months.) Patient agreement to enter the trial 30 to 60 years old patients

Exclusion criteria:
Patients with history of trauma, surgery, corticosteroid injection or any previous injury to the shoulder Patients who had received other treatments including surgical or nonsurgical treatments prior to entering the trial

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Using statistical software, a set of numbers is generated and formed in the form of random permutation blocks with a volume of 4. The two smaller numbers in each block are for patients receiving calcitonin, and the two larger numbers are for patients not receiving calcitonin. Each patient is assigned a number according to the order of enrollment, and depending on whether the number assigned to the patient in the permutation block of 4 is among the large numbers or small numbers, the patient is either in the spray receiving group or the group who do not receive spray.

Blinding (investigator's opinion)
Single blinded

Blinding description
Principal Investigator who initially examines the patients to assess inclusion and exclusion criterion and determines the eligible patients to enter the intervention and visits them in the follow-up process, is unaware of which group the patients are in. Another person divides patients into two groups according to the aforementioned randomization method, the group receiving the spray and the group who do not receive the spray. The data analyzer is also unaware of which group the patients belonged to.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan university of medical science

Street address

No 38, 2nd alley, Mollasadra St.

City

Isfahan

Province

Isfahan

Postal code

8168613441

Approval date

2021-03-19, 1399/12/29

Ethics committee reference number

IR.MUI.MED.REC.1399.1181

Health conditions studied

1

Description of health condition studied

adhesive capsulitis of shoulder

ICD-10 code

M75.0

ICD-10 code description

Adhesive capsulitis of shoulder

Primary outcomes

1

Description

Pain severity

Timepoint

Before starting the intervention, 2 months and 6 months after starting the intervention

Method of measurement

By Visual Analogue Scale(VAS)

2

Description

Shoulder range of motion

Timepoint

Before starting the intervention, 2 months and 6 months after starting the intervention

Method of measurement

By physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: this group receives nasal calcitonin spray. It should be used with dosage of one puff daily for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: this group does not receive calcitonin spray.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Mohammad Dehghani

Street address

Kashani St.

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shakibadehghanii@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Vice President for Research and Technology of
isfahan university of medical science

Street address

Isfahan university of medical science , hezarjarib St.

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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

Esfahan University of Medical Sciences

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

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Dehghani

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

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Latest degree

Subspecialist

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

Esfahan University of Medical Sciences

Full name of responsible person

Shakiba Dehghani

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

Others

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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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data is encrypted in order to make the identities of individuals unidentifiable and confidential

When the data will become available and for how long

after

To whom data/document is available

University Ethics Committee, Project Arbitration Committee, Article Arbitration Committee and other researchers

Under which criteria data/document could be used

systematic review or meta-analysis by mentioning the document

From where data/document is obtainable

Dr. mohammad dehghani

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

After submitting the application via academic email, we will provide the information files to the individuals within a maximum of one month.

Comments