Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Calcitonin effects on shoulder Adhesive capsulitis

Protocol summary

Summary

The aim of this study is to evaluate the effect of Calcitonin on shoulder adhesive capsulitis. In a randomized triple blinded clinical trial, 72 patients with shoulder adhesive capsulitis referring to orthopedic clinic of Shohada Hospital, Tabriz, Iran, will be randomly divided into two groups. The key inclusion criteria are to have shoulder adhesive capsulitis and not to receive any kind of systemic corticosteroid. Exclusion criteria will include occurrence of any intolerable adverse effect. Calcitonin 200 units/mg nasal spray made by Sina Darou Corporation will be administered for intervention group one puff daily for six weeks while patients in control group will receive placebo with the same shape and size of the original drug made by the same manufacturer for the same period. All the individuals will be assessed for the severity of pain, joint range of motion and SPADI, DASH and HAQ scoring before and 3, 6 and 12 weeks after the initiation of the treatment. Then the gathered data will be compared within and between the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013080414271N1**
Registration date: **2013-08-25, 1392/06/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-08-25, 1392/06/03

Registrant information

Name
Alireza Rouhani
Name of organization / entity
Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Calcitonin effects on shoulder Adhesive capsulitis

Public title

Calcitonin in treatment of shoulder capsulitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (To have shoulder adhesive capsulitis; not to have history of surgery or any prior trauma to the shoulder; not to have a systemic disease like diabetes or hypo or hyperthyroidism; not to receive any kind of systemic corticosteroid) Exclusion criteria: (Occurrence of intolerable adverse effects)

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Daneshgah Sq.

City

Tabriz

Postal code

Approval date

2013-04-21, 1392/02/01

Ethics committee reference number

9228

Health conditions studied

1

Description of health condition studied

Shoulder adhesive capsulitis

ICD-10 code

M75.0

ICD-10 code description

Adhesive capsulitis of shoulder

Primary outcomes

1

Description

Pain severity

Timepoint

Before the initiation of the treatment and 3, 6 and 12 weeks after the initiation of the treatment.

Method of measurement

Using Visual Analog Scale

2

Description

Shoulder range of motion

Timepoint

Before the initiation of the treatment and 3, 6 and 12 weeks after the initiation of the treatment.

Method of measurement

Using physical examination

3

Description

DASH score

Timepoint

Before the initiation of the treatment and 3, 6 and 12 weeks after the initiation of the treatment.

Method of measurement

Using DASH questionnaire

4

Description

SPADI score

Timepoint

Before the initiation of the treatment and 3, 6 and 12 weeks after the initiation of the treatment.

Method of measurement

Using SPADI questionnaire

5

Description

HAQ score

Timepoint

Before the initiation of the treatment and 3, 6 and 12 weeks after the initiation of the treatment.

Method of measurement

Using HAQ questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

For intervention group: Calcitonin 200 units/mg nasal spray made by Sina Darou Corporation will be administered for six weeks.

Category

Treatment - Drugs

2

Description

For control group: Placebo nasal spray with the same shape and size of the Calcitonin nasal spray made by Sina Darou one puff daily for sex weeks will be administered.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Clinics of Shohada Hospital

Full name of responsible person
Alireza Rouhani

Street address
Shohada Hospital, Parvaz st.

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person
AliReza Ostad Rahimi

Street address
Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah Avenue, Daneshgah Square

City
Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for research, Tabriz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mahmoud Barzgar

Position
Resident of orthopedics

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty