

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of local ozone injection vs corticosteroid injection in the treatment of shoulder adhesive capsulitis

Protocol summary

Study aim

The aim of this study is to compare the effectiveness of two methods of intra articular injection of Ozone and Corticosteroid in improving pain and function in patients with adhesive capsulitis of the shoulder.

Design

Phase III, randomized, double-blind, parallel-group clinical trial with two week and eight week post injection follow up on 40 patients. Randomization was done through the use of closed envelopes (Envelope A: for Corticosteroid injection and Envelope B: for Ozone injection).

Settings and conduct

Patients with adhesive capsulitis of the shoulder referred to Imam Reza and Shahid Madani Medical Center of Tabriz, who were randomly divided into two groups using the closed envelope method.

Participants/Inclusion and exclusion criteria

The criteria for entering this study: age more than 20 years, diagnosis of shoulder adhesive capsulitis based on shoulder specialized tests such as checking active and passive range of motion, pain intensity based on visual analog scale greater than or equal to 4, consent to enter the study. Exclusion criteria: drug addiction, history of coagulation disorders, rheumatological diseases, history of intra articular injection during the previous three months, use of anticoagulants, hypersensitivity reaction to lidocaine, neck radiculopathy, cellulitis and skin infection at the site Intra articular injection, contraindications of ozone therapy (known cases of glucose 6 phosphate dehydrogenase deficiency, uncontrolled hyperthyroidism, pregnancy and leukemia).

Intervention groups

Two groups including blind ozone and corticosteroid injection groups

Main outcome variables

Pain intensity, degree of functional disability and shoulder range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003217N14**

Registration date: **2022-11-09, 1401/08/18**

Registration timing: **prospective**

Last update: **2022-11-09, 1401/08/18**

Update count: **0**

Registration date

2022-11-09, 1401/08/18

Registrant information

Name

Fariba Eslamian

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 3967

Email address

eslamianf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of local ozone injection vs corticosteroid injection in the treatment of shoulder adhesive capsulitis

Public title

Comparison of the effects of local ozone and corticosteroid injection in the treatment of adhesive capsulitis of the shoulder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age more than 20 years
Diagnosis of shoulder adhesive capsulitis based on specialized shoulder tests such as active and passive ROM
Pain intensity based on VAS criteria is greater than or equal to 4
Consent to enter the study

Exclusion criteria:

Drug addiction
History of coagulation disorders, rheumatological diseases, History of intra-articular injection during the previous three months
Use of anticoagulants
Hypersensitivity reaction to lidocaine
Neck radiculopathy
Cellulitis and skin infection at the site of intra-articular injection
Contraindications for ozone therapy include known cases of G6PD deficiency, uncontrolled hyperthyroidism, pregnancy, and leukemia

Age

From **20 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

A box containing 40 sealed envelopes is selected and group A paper is placed inside 20 envelopes and group B paper is placed inside 20 envelopes. This box is placed in front of patients and one envelope is chosen by each patient. In this way, the patients are completely unaware of the selected group and are randomly assigned to group A (Ozone injection) or group B (Cortone injection).

Blinding (investigator's opinion)

Double blinded

Blinding description

Away from the patient's eyes, the desired injectable substance will be prepared in the syringe and the syringes will be covered with an aluminum sheet so that the person does not know the type of injected substance. Due to the different nature of ozone (gas), during the injection, there is a possibility that the injecting person will understand the nature of this injected substance. The statistical analysis person is also kept blind.

Placebo

Not 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

Daneshgah Ave, executive field of Tabriz University of Medical Sciences, Vice-Chancellor for research of Tabriz University of Medical Sciences, University Ethics Committee

City

Tabriz

Province

East Azarbaijan

Postal code

5123698741

Approval date

2022-10-03, 1401/07/11

Ethics committee reference number

IR.TBZMED.REC.1401.569

Health conditions studied**1****Description of health condition studied**

Adhesive capsulitis of the shoulder

ICD-10 code

M75.0

ICD-10 code description

Adhesive capsulitis of shoulder

Primary outcomes**1****Description**

Pain intensity

Timepoint

Before the intervention, 2 weeks and 8 weeks after the treatment

Method of measurement

Visual analogue scale (VAS)

Secondary outcomes**1****Description**

Shoulder joint range of motion

Timepoint

Before the intervention, 2 weeks and 8 weeks after the treatment

Method of measurement

Goniometry

2

Description

Functional disability of shoulder-related activities

Timepoint

Before the intervention, 2 weeks and 8 weeks after the treatment

Method of measurement

Shoulder Pain and Disability Index (SPADI)

Intervention groups

1

Description

Intervention group: The first intervention group: Ozone with a concentration of 15 micro-gram in the shoulder joint area, blindly and with a posterior approach

Category

Treatment - Other

2

Description

Intervention group: The second intervention group: Methylprednisolone acetate (40 mg) in the shoulder joint area with a posterior approach and blindly

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Fariba Eslamiyan

Street address

Department of physical medicine and rehabilitation,
Emam Reza hospital, Golgasht Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5698745213

Phone

+98 41 3336 1928

Email

eslamiyanf@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

dr Mohammad Samiei

Street address

The end of Golgasht St, Daneshgah St

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3335 7310

Email

Samiei.moh@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Fariba Eslamiyan

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Department of Physical Medicine and rehabilitation,
Imam Reza Hospital, Daneshgah Square, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3337 3967

Email

eslamiyanf@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Fariba Eslamiyan

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Imam Reza Hospital, The end of Golgasht St,
Daneshgah St

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3337 3967

Email

Eslamiyanf@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Rezvan Ghaed Durbash

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

Imam Reza Hospital, The end of Golgasht St,
Daneshgah St

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3337 3967

Email

rezvan.ghaed@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable