

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Comparing ultrasound guided injection of oxygen-ozone vs. corticosteroid vs. prolotherapy in the treatment of shoulder tendinopathy : a randomized, prospective, multicenter randomized clinical trial

#### Protocol summary

##### Study aim

The effect of Sono-guided Oxygen-ozone/ corticosteroid and prolotherapy local injection in the treatment of Shoulder tendonitis

##### Design

Phase 3, multi-center, double blind randomized controlled clinical trial, with parallel group design. The study will be done on 45 patients (15 in each group), and follow-up will be done two week , two months and six months after the injection

##### Settings and conduct

Department of Physical Medicine and Rehabilitation of Firoozgar Hospital and Physiotherapy and Rehabilitation Physics Department of Rasoul Akram Medical Center affiliated to Iran University of Medical Sciences

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Tendinopathy in patients with positive one of the shoulder tests including Neer test or Hawkins test, VAS greater than 4, Patient's desire to attend the research project. Exclusion criteria: rotator cuff tear, diabetes, coagulation disorders, fracture, rheumatologic diseases, tumors and infection, history of Injection in the shoulder joint in the last 3 months, Frozen Shoulder, Presence of c6-c5 Concomitant radiculopathy.

##### Intervention groups

Topical ozone injection group: 5cc ozone 20µg/L  
Corticosteroid injection group: 1cc triamcinolone 40mg + 1cc lidocaine and prolotherapy group: 5cc dextrose 20%

##### Main outcome variables

Visual Analogue Scale (VAS); shoulder pain and disability index (SPADI)

#### General information

##### Reason for update

Modifications are needed in the execution method, date

and place.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151017024572N17**

Registration date: **2018-07-12, 1397/04/21**

Registration timing: **prospective**

Last update: **2025-05-13, 1404/02/23**

Update count: **2**

##### Registration date

2018-07-12, 1397/04/21

##### Registrant information

###### Name

Arash Babaei-Ghazani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6435 2683

###### Email address

babaei-ghazani.a@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-10, 1398/02/20

##### Expected recruitment end date

2024-06-22, 1403/04/02

##### Actual recruitment start date

2019-05-10, 1398/02/20

##### Actual recruitment end date

2024-06-22, 1403/04/02

##### Trial completion date

2024-12-22, 1403/10/02

##### Scientific title

Comparing ultrasound guided injection of oxygen-ozone vs. corticosteroid vs. prolotherapy in the treatment of shoulder tendinopathy : a randomized, prospective, multicenter randomized clinical trial

### Public title

Comparing local injection of ozone, corticosteroid and prolotherapy under ultrasound guidance in the treatment of inflammation of shoulder tendons

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

The presence of tendinopathy in patients as a positive one in a special shoulder test, including: Neer test, Hawkins test Visual Analog Scale (VAS) above 4 Patient's desire to attend research project

#### Exclusion criteria:

Existence of a history and examination of rotator cuff tears, diabetes, coagulation disorders, fractures, rheumatologic diseases, tumors and infection Receiving injection in the shoulder joint in the last 3 months Frozen Shoulder Presence of c6-c5 synchronous radiculopathy

### Age

From **20 years** old to **80 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Data analyser

### Sample size

Target sample size: **45**

Actual sample size reached: **45**

### Randomization (investigator's opinion)

Randomized

### Randomization description

A simple random method for randomization will be used and individuals (patients) will form random units. A random sequence will be generated using RAS software. A central randomization method will be used to conceal random allocation. The random sequence will be created by the statistician and will be available to her. The doctor will be connected to the statistician by telephone or text message and will ask him or her about the random allocation of the participant to the specific group.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

In order to blind the patient, the doctor will prepare the injection material in the syringe, and will cover the syringes with an aluminum sheet to avoid being aware of the type of injection. It should be noted that dilution of corticosteroid and normal saline will be done to equalize the volume of all three injectable solutions. Patients in each group will be evaluated by a physical medicine and rehabilitation specialist, who is not aware of the type of injection, before the injection, two week , two months and six months after the injection.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

##### Street address

Iran University of Medical Sciences, Hemat Highway next to Milad Tower, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۳۹۶۱۴۵۳۵

#### Approval date

2017-07-08, 1396/04/17

#### Ethics committee reference number

IR.IUMS.REC 1396.30322

## Health conditions studied

### 1

#### Description of health condition studied

Inflammation of the shoulder tendons

#### ICD-10 code

G59

#### ICD-10 code description

Mononeuropathy in diseases classified elsewhere

## Primary outcomes

### 1

#### Description

Pain score based on Visual Analogue Scale

#### Timepoint

Before injection, two weeks , two months and six months after the injection

#### Method of measurement

Visual Analog Scale (VAS)

### 2

#### Description

Shoulder pain and disability

#### Timepoint

Before injection, two weeks , two months and six months after the injection

#### Method of measurement

Shoulder pain and disability index (SPADI)

## Secondary outcomes

### 1

#### Description

Clinical Global Impression

#### Timepoint

Before injection, two weeks , two months and six months after the injection

#### Method of measurement

Clinical Global Impression Questionnaire

### 2

#### Description

Patient Global Impression of Improvement

#### Timepoint

Before injection, two weeks , two months and six months after the injection

#### Method of measurement

Patient Global Impression of Improvement Questionnaire

### 3

#### Description

shoulder rang of motiom

#### Timepoint

Before injection, two weeks , two months and six months after the injection

#### Method of measurement

goniometer

### 4

#### Description

Subacromial bursaThickness

#### Timepoint

Before injection, two weeks , two months and six months after the injection

#### Method of measurement

sonography

### 5

#### Description

Constant Score

#### Timepoint

Before injection, two weeks , two months and six months after the injection

#### Method of measurement

Constant Score Questionnaire

## Intervention groups

### 1

#### Description

Intervention group (ozone therapy): 5cc ozone 20µg / L, in subacromial space with lateral aperture under ultrasound guidance.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group (porlotherapy): 5cc dextrose 20%, in subacromial space with lateral aperture under ultrasound guidance.

#### Category

Treatment - Drugs

### 3

#### Description

Control group (corticosteroid therapy ): 1cc triamcinolone 40mg + 1cc lidocaine , in subacromial space with lateral aperture under ultrasound guidance.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of Physical Medicine and Rehabilitation of Rasoul-e-Akram Medical Education Center affli

##### Full name of responsible person

Arash Babaee

##### Street address

Rasoul-e-Akram Hospital, Mazar-i-Mansouri St., Sattarkhan Street

##### City

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##### Province

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##### Postal code

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##### Email

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### 2

#### Recruitment center

##### Name of recruitment center

Shohada Medical Research and Training Hospital,Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. arash babaei

##### Street address

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

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

No

**Title of funding source**

Iran University of Medical Sciences

**Proportion provided by this source**

70

**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

**2****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Seyed Kazem Malakouti

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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**

Iran University of Medical Sciences

**Proportion provided by this source**

30

**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**

Iran University of Medical Sciences

**Full name of responsible person**

Arash Babaie

**Position**

specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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**Position**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Arash Babaei

**Position**

Associate Professor of Physical Medicine and  
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**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

**Street address**

Department of Physical Medicine and Rehabilitation,  
Firuzgar Hospital, Valiasr Square, Tehran

**City**

## 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**

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

**Data Dictionary**

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