

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jul 2026

### The comparison of single session ultrasound-guided ozone and corticosteroid injection in shoulder tendinopathy

#### Protocol summary

##### Study aim

The aim of this study is to evaluate the effect of a single ozone injection in shoulder tendinopathy compared with corticosteroid injections.

##### Design

The study is clinical trial double-blinded (patients and analyzers) study and the sampling is with random blocks method. The study population is 30 patients referred to physical medicine and rehabilitation clinic at Firoozgar hospital.

##### Settings and conduct

patients will be randomly divided into two groups of fifteen. For randomization, we will use a randomized blocking method. The place of execution is physical medicine and rehabilitation clinic at Firoozgar hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age between 20 and 80 years; Shoulder tendinopathy; Visual Analogue Scale (VAS) > 4; The willingness of patients to participate in research projects; The absence history of rotator cuff tear, diabetes, coagulation disorders, fractures, rheumatologic diseases, tumors, and infections; Not having shoulder injection in last 3 months; The absence of intraarticular injection contraindications; The absence of corticosteroid and lidocaine injection contraindications; The absence of ozone injection contraindications. Exclusion criteria: the willingness of patients to exit from the study at any stage of the project; Non-coming patient for follow-ups; Daily use of any type of pain medication for the duration of the study.

##### Intervention groups

Intervention group: Ultrasound-guided injection of ozone in the subacromial space with the lateral approach. Control group: Ultrasound-guided injection of corticosteroid in the subacromial space with the lateral approach.

##### Main outcome variables

The severity of symptoms by Visual Analog Scale (VAS); Shoulder Pain and Disability by Shoulder Pain and

Disability Index (SPADI); IndexThe severity of symptoms and functional limitations of the shoulder by Constant score questionnaire.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016122424572N4**

Registration date: **2017-01-27, 1395/11/08**

Registration timing: **prospective**

Last update: **2018-10-24, 1397/08/02**

Update count: **1**

##### Registration date

2017-01-27, 1395/11/08

##### 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

Vice chancellor for research, Iran University of Medical Sciences

##### Expected recruitment start date

2016-10-16, 1395/07/25

##### Expected recruitment end date

2017-06-15, 1396/03/25

##### Actual recruitment start date

2017-02-01, 1395/11/13  
**Actual recruitment end date**  
 2017-10-03, 1396/07/11  
**Trial completion date**  
 2018-01-05, 1396/10/15

**Scientific title**  
 The comparison of single session ultrasound-guided ozone and corticosteroid injection in shoulder tendinopathy

**Public title**  
 The comparison of effects of ozone and corticosteroids injection in treatment of shoulder inflammatory diseases

**Purpose**  
 Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Age between 20 and 80 years; Shoulder tendinopathy as positive result of specific test like Neer & Hawkins test; Visual Analogue Scale (VAS) > 4; The willingness of patients to participate in research projects; The absence history of rotator cuff tear, diabetes, coagulation disorders, fractures, rheumatologic diseases, tumors, and infections; Not having shoulder injection in last 3 months; The absence of intraarticular injection contraindications like anticoagulant medications consumption; The absence of corticosteroid and lidocaine injection contraindications such as allergy reaction to these medications and skin infection at the injection site; The absence of ozone injection contraindications such as G6PDD, uncontrolled hyperthyroid, the first 3 months of pregnancy, leukemia.  
**Exclusion criteria:**  
 The willingness of patients to exit from the study at any stage of the project; Noncoming patient for follow-up and evaluation during the follow-up study; Daily use of any type of pain medication by patients for the duration of the study.

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

**Gender**  
 Both

**Phase**  
 N/A

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**  
 Target sample size: **30**  
 Actual sample size reached: **30**

**Randomization (investigator's opinion)**  
 Randomized

**Randomization description**  
 Method of randomization: block, Unit of randomization: individual, Tools used in randomization: table of random numbers.

**Blinding (investigator's opinion)**  
 Double blinded

**Blinding description**  
 This is a double-blind study in which patients and

outcomes analyzer are blinded. In order to blind the patient, it is said that both materials are effective for treatment, but the type of substance is not mentioned for patients when its injected. In order to blind the analyzer, the persons responsible for injection and data collection are different from the outcome assessors.

**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 Science  
**Street address**  
 Medical faculty, Iran University of Medical Science, Hemmat High way  
**City**  
 Tehran  
**Province**  
 Tehran  
**Postal code**  
 1449614535  
**Approval date**  
 2016-10-16, 1395/07/25  
**Ethics committee reference number**  
 IR.IUMS.REC 1395.9411524003

## Health conditions studied

### 1

**Description of health condition studied**  
 Shoulder tendinopathy  
**ICD-10 code**  
 M75.4  
**ICD-10 code description**  
 Impingement syndrome of shoulder

## Primary outcomes

### 1

**Description**  
 The severity of symptoms  
**Timepoint**  
 Zero, two weeks and two months after  
**Method of measurement**  
 Visual Analog Scale (VAS)

### 2

**Description**

Shoulder Pain and Disability Index  
**Timepoint**  
Zero, two weeks and two months after  
**Method of measurement**  
SPADI questionnaire

### 3

**Description**  
The severity of symptoms and functional limitations  
**Timepoint**  
Zero, two weeks and two months after  
**Method of measurement**  
Constant score questionnaire

## Secondary outcomes

### 1

**Description**  
Side effects  
**Timepoint**  
Two weeks and two months after  
**Method of measurement**  
Physical examination

## Intervention groups

### 1

**Description**  
Control group: Ultrasound-guided injection of corticosteroid in the subacromial space with lateral approach  
**Category**  
Treatment - Other

### 2

**Description**  
Intervention group: ULtrasound-guided injection of ozone in the subacromial space with lateral approach  
**Category**  
Treatment - Other

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Firoozgar Hospital  
**Full name of responsible person**  
Mohammad Sadegh Khabbaz  
**Street address**  
Department of Physical Medicine and Rehabilitation,  
Firuzgar Hospital, Valiasr Square  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**

1593747811  
**Phone**  
+98 21 8214 1201  
**Email**  
m.sadegh.khabbaz@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Dr Motovalian  
**Street address**  
5th floor, Headquarters, Iran University of Medical Sciences, Hemmat Highway, Tehran  
**City**  
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**Province**  
Tehran  
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+98 21 8214 1229  
**Email**  
m.sadegh.khabbaz@gmail.com  
**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**  
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**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Mohammad Sadegh Khabbaz  
**Position**  
Resident of Physical Medicine and Rehabilitation  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Physical Medicine  
**Street address**  
Department of Physical Medicine and Rehabilitation,

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Dr. Arash Babaei

**Position**

Associate Professor of Physical Medicine and Rehabilitation

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Mohammad Sadegh Khabbaz

**Position**

Resident of Physical Medicine and Rehabilitation

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

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**Email**

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**Web page address**

## 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 the patient's data can be shared with privacy in regard to patients name

**When the data will become available and for how long**

Start accessing 6 months after publishing the results.

**To whom data/document is available**

For scholars working in academic centers.

**Under which criteria data/document could be used**

It can be analyzed and printed by other people by mentioning the source.

**From where data/document is obtainable**

Dr. Mohammad Sadegh Khabbaz, 00989112840455,  
m.sadegh.khabbaz@gmail.com.

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

Upon authentication, data is provided to the individual.

**Comments**