

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Intra Articular Ozone or Hyaluronic Acid Injection: Which One is Superior in Patients with Knee Osteoarthritis? a 6-Month Randomized Clinical Trial

#### Protocol summary

##### Summary

**Objectives:** The aim of this study is to compare efficacy and safety of ozone therapy versus hyaluronic acid (HA) intra articular injection in patients with knee OA. **Study Design:** Double blind Randomized controlled clinical trial **Setting and Conduct:** In this study a total of 174 patients with more than three months of chronic pain in the knee joints along with consistent imaging findings (Kellgren-Lawrence score of II&III) would be enrolled and randomly allocated into two groups of ozone and HA. **Participants:** Patients suffering from mild to moderate knee OA referred to Shahid Modarres Hospital of Saadat Abad in Tehran in 2016 **Interventions:** Three weekly injections of Hyalgan® in one group and 10 ml of a 30 µg/ml ozone solution in other group. **Outcome measurers:** Patients would be evaluated at baseline and 6 months after the last injection for pain, stiffness and function using the Visual Analog Scale (VAS) and the Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017041513442N16**

Registration date: **2017-08-28, 1396/06/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-08-28, 1396/06/06

##### Registrant information

###### Name

Seyed Ahmad Raeissadat

###### Name of organization / entity

Modares Hospital

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2273 1112

###### Email address

a\_raeissadat@sbmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Physical Medicine and Rehabilitation Department of Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2016-01-01, 1394/10/11

##### Expected recruitment end date

2016-07-01, 1395/04/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Intra Articular Ozone or Hyaluronic Acid Injection: Which One is Superior in Patients with Knee Osteoarthritis? a 6-Month Randomized Clinical Trial

##### Public title

Intra Articular Ozone or Hyaluronic Acid Injection: Which One is Superior in Patients with Knee Osteoarthritis? a 6-Month Randomized Clinical Trial

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria: age between 45-75 years; symptomatic knee OA with the pain aggravated by weight bearing; symptoms lasting for at least 6 months despite conservative treatments; Kellgren-Lawrance radiologic scoring (KLS) system scores ranging from 2-3

Exclusion Criteria: history of trauma, surgery or any invasive procedure in the affected joint during the past 6 months; mal-alignment in lower limbs and abnormal blood count or impaired coagulation tests; pregnant women; patients who were under immunosuppressant treatments; those with an underlying systemic arthropathy (secondary OA); patients being treated with angiotensin converting enzyme inhibitors (ACEI) and significant deficiency in glucose 6-phosphate dehydrogenase (G6PD) level

#### Age

From **45 years** old to **75 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **174**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic Committee of Shahid Beheshti University of Medical Sciences

##### Street address

Shahid Beheshti University of Medical Sciences,  
Sahahid Arabi street, Yaman street, Shahid Chamran  
Highway

##### City

Tehran

##### Postal code

#### Approval date

2017-08-15, 1396/05/24

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1396.237

## Health conditions studied

### 1

#### Description of health condition studied

knee osteoarthritis

#### ICD-10 code

M17

#### ICD-10 code description

Gonarthrosis [arthrosis of knee]

## Primary outcomes

### 1

#### Description

knee pain

#### Timepoint

before intervention & 6 months after last intervention

#### Method of measurement

WOMAC questionnaire

## Secondary outcomes

### 1

#### Description

Patient Function

#### Timepoint

before intervention & 6 months after intervention

#### Method of measurement

WOMAC questionnaire

### 2

#### Description

knee pain

#### Timepoint

before intervention & 6 months after intervention

#### Method of measurement

VAS

### 3

#### Description

joint stiffness

#### Timepoint

before intervention & 6 months after intervention

#### Method of measurement

WOMAC questionnaire

## Intervention groups

### 1

#### Description

Intervention group 1: Hyaluronic acid, knee intraarticular injection, 20mg/2ml solution, 3 times, 1 week interval

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: Ozone-Oxygen solution, knee intraarticular injection, 10 milliliter, 3 times, 1 week interval

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Modarres Hospital

**Full name of responsible person**

Shahram Rahimi-Dehgolan

**Street address**

Shahid Modarres Hospital, Kaj square, Saadat Abad street

**City**

Tehran

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

Physical Medicine and Rehabilitation Department of Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Vice chancellor for research, Seyed Ahmad Raeissadat

**Street address**

Physical Medicine and Rehabilitation Department, Shahid Modarres Hospital, Kaj square, Saadat abad

**City**

Tehran

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

Yes

**Title of funding source**

Physical Medicine and Rehabilitation Department of Shahid Beheshti 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**

Physical Medicine and Rehabilitation Department, Shahid Beheshti University of Medical Sciences, Sch

**Full name of responsible person**

Shahram Rahimi Dehgolan

**Position**

Physical Medicine and Rehabilitation resident

**Other areas of specialty/work****Street address**

Shahid Modarres hospital, Kaj square, Saadat abad street

**City**

Tehran

**Postal code****Phone**

+98 21 2273 1112

**Fax****Email**

shahram.rahimi.dehgolan@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Modarres Hospital

**Full name of responsible person**

Seyed Ahmad Raeissadat

**Position**

Associate Professor

**Other areas of specialty/work****Street address**

Shahid Modarres Hospital, Kaj square, Saadat Abad street

**City**

Tehran

**Postal code****Phone**

+98 21 2207 4090

**Fax****Email**

a\_raeissadat@sbmu.ac.ir

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

Shahid Modarres Hospital

**Full name of responsible person**

Seyed Ahmad Raeissadat

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Associate Professor

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+98 21 2207 4090

**Fax****Email**

a\_raeissadat@sbmu.ac.ir

**Web page address**

## **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*