

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

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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

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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

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

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Associate Professor

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Full name of responsible person

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Position

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City

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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