Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 refered 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 measuers: 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 questionnair

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 intraarticuar injection, 20mg/2ml solution, 3 times, 1 week interval

Category
Treatment - Drugs

2

Description
Intervention group 2: Ozone-Oxygen solution, knee intraarticuar 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
Position
Associate Professor
Other areas of specialty/work
Street address
Modares 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

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