Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Evaluation of the effectiveness of prolotherapy with hypertonic dextrose versus hypertonic saline on patients with knee osteoarthritis

Protocol summary

Summary

The aim of this study is evaluation of the effectiveness of prolotherapy with hypertonic dextrose versus hypertonic saline on patients with knee osteoarthritis. This is a multicenter, double blind randomized clinical trial. We will enroll 60 patients with knee osteoarthritis. Participants will randomly be assigned into intervention and control groups and will receive intra-articular injection with 4mL of 50% dextrose and 4mL of 2% lidocaine and intra-articular injection with 4mL of 5% sodiumchloride and 4mL of 2% lidocaine respectively. As the primary outcome of our study, the Visual Analog Scale (VAS) questionnaire will be measured before and 2 weeks and 4 weeks after intervention. We will also measure Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC), and Oxford Knee Scale (OKS) before and 2 weeks and 4 weeks after intervention. Finally, we will compare the results between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122931458N1**
Registration date: **2017-02-06, 1395/11/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-06, 1395/11/18

Registrant information

Name

Ebrahim Mostaghni

Name of organization / entity

International Branch_Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 3635 0446

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of prolotherapy with hypertonic dextrose versus hypertonic saline on patients with knee osteoarthritis

Public title

Effect of prolotherapy with hypertonic dextrose versus hypertonic saline on knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with osteoarthritis of knee who experience joint symptoms (pain, stiffness and reduced function) during one recent month; aged between 40-70 years. Exclusion criteria: rheumatology diseases; radiculopathy; history of trauma and fracture in knees; diabetes; coagulopathy disorders; pregnant women; body mass index (BMI) more than 42.

Age
From **40 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
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
Ethics Committee of Shiraz University of Medical Sciences
Street address
Headquarters Of Shiraz University of Medical Sciences - Zand St - Shiraz
City
Shiraz
Postal code
Approval date
2016-11-02, 1395/08/12
Ethics committee reference number
IR.SUMS.MED.REC.1395.51

Health conditions studied

1

Description of health condition studied
Osteoarthritis of knee
ICD-10 code
M17
ICD-10 code description
Gonarthrosis [arthrosis of knee]

Primary outcomes

1

Description
Questionnaire of Visual Analog Scale
Timepoint
Before intervention, 2 weeks after intervention, 4 weeks after intervention
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Questionnaire of Western Ontario & McMaster Universities Osteoarthritis Index
Timepoint
Before intervention, 2 weeks after intervention, 4 weeks after intervention
Method of measurement
Questionnaire

2

Description
Questionnaire of Oxford Knee Scale
Timepoint
Before intervention, 2 weeks after intervention, 4 weeks after intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Intra-articular injection with 4mL of 50% dextrose and 4mL of 2% lidocaine
Category
Treatment - Drugs

2

Description
Control group: Intra-articular injection with 4mL of 5% Sodium Chloride and 4mL of 2% lidocaine
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Chamran Hospital
Full name of responsible person
Hamid Reza Farpour
Street address
Shahid Chamran blvd
City
Shiraz

2

Recruitment center
Name of recruitment center
Emam Reza Clinic
Full name of responsible person
Hamid Reza Farpour
Street address
Namazi square
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University Of medical Science
Full name of responsible person
Dr Seyed Baser Hashemi
Street address
Building of Shiraz University of Medical Sciences, Zand Ave
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University Of medical Science
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
Shiraz University of Medical Sciences
Full name of responsible person
Hamid Reza Farpour
Position
assistant Professor
Other areas of specialty/work
Street address
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Person responsible for updating data

Contact
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International Branch_Shiraz University of Medical Sciences
Full name of responsible person
Ebrahim Mostaghni
Position
Medical Student
Other areas of specialty/work
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City
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Phone
00
Fax
Email
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