Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative effectiveness of prolotherapy with hypertonic saline versus ozone and hypertonic saline combination in reduce pain and functional improvements of osteoarthritis patients

Protocol summary

Study aim

Effectiveness of prolotherapy with hypertonic saline versus ozone and hypertonic saline combination in reduce pain and functional improvements of osteoarthritis patients

Design

A concealed, randomized, double blinded, is designed on 10 patients in the control group and 10 patients in the parallel group

Settings and conduct

This study in the rehabilitation field and is done in imam reza clinic in the shiraz province. Patients and the person evaluating the treatment are unaware of the allocation of treatment due to the lack of distinction between the two types of injections

Participants/Inclusion and exclusion criteria

Grades 1 or 2 osteoarthritis base on Kellgren- Lawrence radiographic Criterion;Osteoarthritis pain more than three month;Any type of intra-articular injection or prolothrapy in the one past year;Grades 3 or 4 osteoarthritis base on Kellgren- Lawrence radiographic Criterion;Knee surgery

Intervention groups

In Intervention group: Intra-articular injection of 4 ml saline 5% plus 4 ml of lidocaine 2% in the knee With the injection of 7 ml of Ozone at a concentration of 20 µg / ml with lifestyle correction and suitable exercises for knee pain. 3 steps injection are done within 2 weeks and in Control group: Intra-articular injection of 4 ml saline 5% plus 4 ml of lidocaine 2% in the knee with lifestyle correction and suitable exercisees for knee pain. 3 steps injection are done within 2 weeks.

Main outcome variables

Pain;Function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180127038527N1**
Registration date: **2018-02-19, 1396/11/30**
Registration timing: **retrospective**

Last update: **2018-02-19, 1396/11/30**
Update count: **0**

Registration date

2018-02-19, 1396/11/30

Registrant information

Name

seyed saeeid hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3228 7904

Email address

hsni.saeeid@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparative effectiveness of prolotherapy with hypertonic saline versus ozone and hypertonic saline combination in reduce pain and functional improvements of osteoarthritis patients

Public title
effectiveness of prolotherapy in reduce pain and functional improvements of osteoarthritis patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Grades 1 or 2 osteoarthritis base on Kellgren- Lawrence radiographic Criterion Osteoarthritis pain for more than three month
Exclusion criteria:
Any type of intra-articular injection or prolothrapy in the one past year Knee surgery Grades 3 or 4osteoarthritis base on Kellgren- Lawrence radiographic Criterion
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients were randomly selected and using a flip the coin method to create a random sequence in such a way that one of the study groups is considered to be the heads and the other group tails , and based on the sample size ,flip the coin , Allocation concealment done with sequentially numbered, sealed, opaque envelopes
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients and the person evaluating the treatment are unaware of the allocation of treatment due to the lack of distinction between the two types of injections.
Placebo
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
Central Building of Shiraz University of Medical Sciences, Zand Ave, Shiraz
City
shiraz
Province
Fars
Postal code
7134814336
Approval date
2017-12-18, 1396/09/27
Ethics committee reference number
ir.sums.med.rec..1396.106

Health conditions studied

1

Description of health condition studied
Osteoarthritis of knee
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
pain
Timepoint
Before and after the intervention in weeks 2 and 4 after the last injection
Method of measurement
visual analog scale

2

Description
Function
Timepoint
Before and after the intervention in weeks 2 and 4 after the last injection
Method of measurement
oxford knee scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intra-articular injection of 4 ml saline 5% plus 4 ml of lidocaine 2% in the knee With the injection of 7 ml of Ozone at a concentration of 20 µg /

ml with lifestyle correction and suitable exercises for knee pain. 3 steps injection are done within 2 weeks.

Category

Treatment - Drugs

2

Description

Control group: Intra-articular injection of 4 ml saline 5% plus 4 ml of lidocaine 2% in the knee with lifestyle correction and suitable exercisees for knee pain. 3 steps injection are done within 2 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza clinic

Full name of responsible person

Hamidreza Farpour

Street address

Namazi SQ,Shiraz

City

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Province

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71348714737

Phone

+98 71 3212 7001

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emamreza@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Basir Hashemi

Street address

Central building of Shiraz University of Medical Sciences,Zand Ave

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71345-1978

Phone

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Email

hashemib@sums.ac.ir

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 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

Shiraz University of Medical Sciences

Full name of responsible person

Saeeid Hosseini

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Position

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Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available