

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 prolotherapy 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 exercises 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 saeed hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3228 7904

Email address

hsni.saeed@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 prolotherapy 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 exercises 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

Shiraz

Province

Fars

Postal code

71348714737

Phone

+98 71 3212 7001

Email

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

City

Shiraz

Province

Fars

Postal code

71345-1978

Phone

+98 71 3235 7282

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

Saeed Hosseini

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Jomhuri bvld, shiraz

City

Shiraz

Province

Fars

Postal code

7144846756

Phone

+98 71 3228 7904

Email

hsni.saeed@gmail.com

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

Shiraz University of Medical Sciences

Full name of responsible person

Saeed Hosseini

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Jomhuri bvld, shiraz

City

Shiraz

Province

Fars

Postal code

7144846756

Phone

+98 71 3228 7904

Email

hsni.saeed@gmail.com

Phone

+98 71 3228 7904

Email

hsni.saeed@gmail.com

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

Shiraz University of Medical Sciences

Full name of responsible person

Saeed Hosseini

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Jomhuri bvld,shiraz

City

Shiraz

Province

Fars

Postal code

7144846756

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