

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of efficacy of intra articular injection of mannitol versus hypertonic dextrose prolotherapy on decreasing pain and improvement of functions in patients with knee osteoarthritis

Protocol summary

Study aim

Evaluation of efficacy of intra articular injection of mannitol versus hypertonic dextrose prolotherapy on decreasing pain and improvement of function in patients with knee osteoarthritis randomized clinical trial

Design

This research is a randomized double-blind, controlled clinical trial

Settings and conduct

The patient select from emam reza clinic and rajae hospital who has knee osteoarthritis. then patient divided into two groups and after obtaining written consent the study begins. in control group hypertonic dextrose is injected and in intervention group mannitol is injected then we measure its effect on reducing pain and improving patient function

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 38 to 75 years; both genders; knee radiography anterior standing view have been for the last one month; have symptoms of osteoarthritis include pain, crepitation, and knee joint dryness for at least a month without any extra-articular involvement; any injection of the knee joint during the last three months. Exclusion criteria: sensitivity reaction to test drug; the patient has done total knee arthroplasty; the patient have diseases mimicking the symptoms of knee pain such as neuropathy and radiculopathy; diseases such as rheumatoid arthritis, Reiter's syndrome, gout; uncontrolled diabetes, HbA1c more than 7.5, BMI more than 40; history of knee trauma, fracture patient's mental disorder.

Intervention groups

Intervention group: group that receive knee intra articular injection of mannitol control group: group that receive knee intra articular injection of hypertonic Dextrose.

Main outcome variables

pain, Activity of daily living

General information

Reason for update

wrong translation

Acronym

IRCT registration information

IRCT registration number: **IRCT20190912044756N1**

Registration date: **2020-08-24, 1399/06/03**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-13, 1400/11/24**

Update count: **2**

Registration date

2020-08-24, 1399/06/03

Registrant information

Name

Nasrin Barzegar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3648 6787

Email address

dr.nasrin.barzegar1975@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-20, 1399/02/31

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of intra articular injection of mannitol versus hypertonic dextrose prolotherapy on decreasing pain and improvement of functions in patients with knee osteoarthritis

Public title

Evaluation of efficacy of intra articular injection of mannitol in patient with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age: 38 to70 years old Gender: male or female Knee radiography anterior standing view have been for the last three month Have symptoms of osteoarthritis include pain, crepitation for at least a month without any extra articular involment

Exclusion criteria:

Any injection of the knee joint during the last three of months sensitivity reaction to test drug The patient have done total knee arthroplasty The patient have diseases mimicking the symptoms of knee pain such as neuropathy and radiculopathy Diseases such as rheumatoid arthritis, Reiter's syndrom, gout Uncontrolled diabetes,HBA1c more than7.5, BMI more than 40 History of knee trauma,fracture Patient's mental disorder

Age

From **38 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **2**

If both knee are involve,one knees in the intervention group and the other is in the control group

Randomization (investigator's opinion)

Randomized

Randomization description

Complete randomize block design with SSPP software is used for randomization and then sealed non-transparent envelopes are used to hide the random sequence

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant: The participant is explained that if they are interested, they can join our research project. two methods used to reduce patient pain input study are explained to the patient. Benefits and possible complications of both methods are described to the patient and the patient is told to randomly fall into one of the intervention groups. If the patient is accepted to admit the study, by random allocation soft ware, the

patient falls in to one of two groups. Clinical car giver: we teach the caregiver how to complete the questionnaire. This person is not aware of receiving patient intervention. Researcher: In this study does not have the ability to blind the reseacher because the researcher performs both intervention himself and is aware of receiving each intervention in the group. The outcome assessor of the complete questionnaires is given to person who is not aware of the interventions performed and he/she is asked to determine the level of performance in each person according to the questionnaires. Date analyzer: questionnaire are finally given to a person to review the information. This person doesn't know any of the steps of the work, how to classify and the intervention performed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz School of Medicin

Street address

No.11, Ansar Ave., Koohbor Blvd., Zerehi

City

Shiraz

Province

Fars

Postal code

7184747811

Approval date

2019-07-28, 1398/05/06

Ethics committee reference number

IR.SUMS.MED.REC.1398.314

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

knee pain

Timepoint

Two weeks ,four weeks, eight weeks

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

Function of patient

Timepoint

two weeks, four weeks, eight weeks

Method of measurement

Oxford knee score

Intervention groups**1****Description**

Intervention group: the group that receive 5cc mannitol 5%, knee intra articular injection ,in three doses as the first dose and two weeks, four weeks , weeks after first dose and control group that receive 5cc of dextrose 25%,inter articular injection,as sequence of intervention group.

Category

Rehabilitation

2**Description**

Control group: group who received knee intra articular injection of hypertonic dextrose

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam reza rehabilitation clinic

Full name of responsible person

Mani Ramzi

Street address

Namazi square

City

Shiraz

Province

Fars

Postal code

714737-71348

Phone

+98 71 3212 7000

Email

motahari@sums.ac.ir

Web page address**2****Recruitment center****Name of recruitment center**

Rajae hospital

Full name of responsible person

Amir Reza Mesbahi

Street address

Chamran Blvd

City

Shiraz

Province

Fars

Postal code

7194815711

Phone

+98 71 3636 4001

Fax**Email**

Rajaeehospital@sums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr Ghasemi

Street address

Khalili Aveno, front of Maaref school

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3628 1506

Email

Info@sums.ac.i

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

Nasrin Barzegar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

No.11 , Ansar Ave., koohbor Blvd., Zerehi

City

Shiraz

Province

Fars

Postal code

7184747811

Phone

+98 71 3648 6787

Email

Dr.nasrin.barzegar1975@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Nasrin Barzegar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

No.11., Ansar Avn., koohbor Blvd., Zerehi

City

Shiraz

Province

Fars

Postal code

7184747811

Phone

00986486787

Email

Dr.nasrin.barzegar1975@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Nasrin Barzegar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

No11., AnsarAve ., koohbor Blvd., Zerehi

City

Shiraz

Province

Fars

Postal code

7184747811

Phone

+98 71 3648 6787

Email

Dr.nasrin.barzegar1975@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All available data can be shared after making people unidentifiable.

When the data will become available and for how long

Start access period one year after publishing the results.

To whom data/document is available

everyone can access to this information.

Under which criteria data/document could be used

if the information in this study helps to improve the science process.

From where data/document is obtainable

dr.nasrin.barzegar1975@gmail.com 00989173092357

What processes are involved for a request to access data/document

After sending the desired message, all authors of the study will be consulted all information will be sent within a maximum of three weeks if permitted.

Comments