

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Effects of Prolotherapy with Hypertonic Dextrose in Patients with Osteoarthritis of the Knee: A Randomized Clinical Trial

Protocol summary

Study aim

Pain reduction and improving function and quality of life in patients with osteoarthritis of the knee after prolotherapy

Design

Clinical trial with control group, parallel groups, triple blind, randomized, phase 3 on 80 patients. Randomization by table random number and Clinical C software.

Settings and conduct

Patients referred to the clinic of Ghaem and Imam Reza hospitals and professors' offices in Mashhad

Participants/Inclusion and exclusion criteria

Major inclusion criteria before randomization: all patients with mild to moderate knee osteoarthritis aged 45-75 years according to Kellgren-Lawrence criteria and rheumatologist approval; absence of rheumatic diseases such as Rheumatoid Arthritis; pain and tenderness of the knee joint resistant to medicine and conservative therapy for 3 months. Major exclusion criteria before randomization: pregnancy; allergy to Oxycodone and Lidocaine; $40\text{kg/m}^2 < \text{BMI}$; history of previous prolotherapy; loosening of ligaments and knee joint; history of diabetes; history of hematologic disease especially with thrombocytopenia; history of taking anticoagulants such as Plavix and warfarin; history of joint injection in the last 3 months; history of inflammatory joint disease and history of knee joint infection; people who are candidates for knee surgery with grade 4 based on Kellgren-Lawrence; history of joint replacement and presence of joint prosthesis

Intervention groups

Injection of 5% and 25% dextrose in the knee joint in 40 patients with mild to moderate knee osteoarthritis in the age range of 45-75 years

Main outcome variables

Scores of WOMAC and KPS questionnaires; clinical and functional status of the joint and persistence of the drug for 6 months after ending the treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190921044831N2**

Registration date: **2021-10-29, 1400/08/07**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-29, 1400/08/07**

Update count: **0**

Registration date

2021-10-29, 1400/08/07

Registrant information

Name

Farima Minaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3893 4320

Email address

minaee.farima@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Prolotherapy with Hypertonic Dextrose in Patients with Osteoarthritis of the Knee: A Randomized Clinical Trial

Public title

Effectiveness evaluation of hypertonic dextrose therapy in knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with mild to moderate knee osteoarthritis aged 45-75 years according to Kellgren-Lawrence criteria and rheumatologist approval Absence of rheumatic diseases such as Rheumatoid Arthritis Pain and tenderness of the knee joint resistant to medicine and conservative therapy for 3 months

Exclusion criteria:

Pregnancy Medicine allergy to Oxycodone and Lidocaine 40kg/m²<BMI History of previous prolotherapy Loosening of ligaments and knee joint History of diabetes History of hematologic disease, especially with palpitations History of taking anticoagulants such as Plavix and warfarin History of joint injection in the last 3 months History of inflammatory joint disease and history of knee joint infection People who are candidates for knee surgery with grade 4 based on Kellgren-lawrence History of joint replacement and presence of joint prosthesis

Age

From **45 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization based on a random number table

Blinding (investigator's opinion)

Triple blinded

Blinding description

Preparation and allocation of drugs (25% dextrose) and placebo (normal saline 0.9%) were performed by a nurse, therefore, patients in both control and intervention groups. The rheumatologist who was injecting and the data analyzer were blinded to the condition.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethics Committee of Mashhad University of Medical Sciences

Street address

Azadi Square, east door of the university campus

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2021-08-29, 1400/06/07

Ethics committee reference number

IR.Mums.Rec.1400.153

Health conditions studied

1

Description of health condition studied

Knee Osteoarthritis

ICD-10 code

M15.0

ICD-10 code description

Primary generalized (osteo)arthritis

Primary outcomes

1

Description

Score of WOMAC questionnaire

Timepoint

4, 8, 12, 16, 20, 24 weeks after injection

Method of measurement

Score of WOMAC questionnaire

Secondary outcomes

1

Description

Clinical and functional status of the joint and persistence of the drug for 6 months after ending the treatment

Timepoint

6 months after ending the treatment

Method of measurement

Questionnaire and clinical assessment

Intervention groups

1

Description

Intervention group: 80 patients with mild to moderate osteoarthritis of the knee aged 75-45 years for whom the diagnosis was made by physical examination and knee AP graphy according to the criterion (grade lawrence-kellgren) by a rheumatologist based on the inclusion criteria. the patients who were referred to the clinic of Ghaem and Imam Reza hospitals and the specialists' office in Mashhad were selected and after filling out the consent form, they entered the study. they were followed up for 24 weeks. The sample selection was done through random numbers and the consort chart. For each patient, first, sufficient explanations are given about the plan and performance of it and also, the benefits of the injection and the possible side effects of it. The consent form and womac and (scale pain knee) Kps are completed and before starting the procedure, an oxycodone 30 mg tablet is prescribed by Farman Shimi Pharmaceutical Company. The syringes were prepared by a nurse who is not aware of the content of Syringes. syringes in the intervention group contained 5% dextrose and 25% dextrose from Samen Pharmaceutical Company (Mashhad-Iran). In supine position and in the knee with flexion of 10 to 15 degrees, intraarticularly by lateral approach method, under sterile conditions, injection of 6 cc of 25% dextrose solution with 2 cc of lidocaine Caspian vial injected with 22 g needle and 20 cc 5% dextrose solution with lidocaine is injected into the tissues and ligaments around it. The injection is given monthly for 3 months. Injectable dextrose in the knee is not a complication and, if present, includes local pain and a small accumulation of fluid in the tissue at the injection site, and rarely rash, urticaria, and itching at the injection site; It is a muscle cramp and paresthesia that all patients are given full explanations about the side effects of the drug so that in case of any of the side effects, they can immediately call the phone number given by the treating physician or, if possible, visit in person to relieve pain symptoms. And swelling of the injection site is given to NSAID patients and if necessary, the NSAID form is given and the patients' follow-up is done at intervals of 4, 8, 12, 16, 20 and 24 weeks after the injection and the KPS and WOMAC questionnaires are filled out. Patients are advised to take acetaminophen as needed for a week and have a relative rest for the first three days. Patients are also advised to avoid analgesic NSAIDs and dietary supplements if possible during treatment. In case of severe need, indicate the number of days and days of drug use in the form of medication delivered to the patient and refrain from physiotherapy during treatment and do not use NSAIDs 48 hours before referral and injection. Clinical status and function of the patient with a questionnaire womac, Kps are checked in person at each visit and in weeks 4, 8, 12, 16, 20 and 24 and patients are given a mobile number and a landline number.

Category

Treatment - Drugs

2

Description

Control group: 80 patients with mild to moderate osteoarthritis of the knee aged 75-45 years for whom the diagnosis was made by physical examination and knee AP graphy according to the criterion (grade lawrence-kellgren) by a rheumatologist based on the inclusion criteria. the patients who were referred to the clinic of Ghaem and Imam Reza hospitals and the specialists' office in Mashhad were selected and after filling out the consent form, they entered the study. they were followed up for 24 weeks. The sample selection was done through random numbers and the consort chart. For each patient, first, sufficient explanations are given about the plan and performance of it and also, the benefits of the injection and the possible side effects of it. The consent form and womac and (scale pain knee) Kps are completed and before starting the procedure, an oxycodone 30 mg tablet is prescribed by Farman Shimi Pharmaceutical Company. The syringes were prepared by a nurse who is not aware of the content of Syringes. The syringes in the control group contained Normal Saline 0.9% Samen Pharmaceutical Company (Mashhad-Iran). In supine position and in the knee with flexion of 10 to 15 degrees, intraarticularly by lateral approach method, under sterile conditions, injection of the present, includes local pain and a small accumulation of fluid in the tissue at the injection site, and rarely rash, urticaria, and itching at the injection site; It is a muscle cramp and paresthesia that all patients are given full explanations about the side effects of the drug so that in case of any of the side effects, they can immediately call the phone number given by the treating physician or, if possible, visit in person to relieve pain symptoms. And swelling of the injection site is given to NSAID patients and if necessary, the NSAID form is given and the patients' follow-up is done at intervals of 4, 8, 12, 16, 20 and 24 weeks after the injection and the KPS and WOMAC questionnaires are filled out. Patients are advised to take acetaminophen as needed for a week and have a relative rest for the first three days. Patients are also advised to avoid analgesic NSAIDs and dietary supplements if possible during treatment. In case of severe need, indicate the number of days and days of drug use in the form of medication delivered to the patient and refrain from physiotherapy during treatment and do not use NSAIDs 48 hours before referral and injection. Clinical status and function of the patient with a questionnaire womac, Kps are checked in person at each visit and in weeks 4, 8, 12, 16, 20 and 24 and patients are given a mobile number and a landline number.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital in Mashhad

Full name of responsible person

Maasoumeh salari

Street address

Imam Reza Research and Treatment Center, Imam Reza Hospital, Ibn Sina St.

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9137913316

Phone

+98 51 3854 3031

Email

imamreza@mshmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaqodi

Street address

Ghorashi Building, Next to Hoveyzeh Cinema, Daneshgah Street

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Phone

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Email

vcresraech@mums.ac.i

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Maasoomeh Salari

Position

Associated Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Maasoomeh Salari

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Parisa Nourabadi

Position

Assistant Fellowship

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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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

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

How to sample, number of participants, how to group

When the data will become available and for how long

after publishing the Extracted article

To whom data/document is available

Researchers who have evidence of intent to use documentation in new research

Under which criteria data/document could be used

Submitting the code of ethics and the code of approval of the proposal related to the new research requires the documents of this study

From where data/document is obtainable

Scientific responsible for the trial

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

Sending Email to the author of the article containing the official request and the code of ethics and the code of approval of their proposal, coordination with the ethics committee of Mashhad University, the consent of all project collaborators and finally making the information available to the researcher

Comments