

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of periarticular & intrarticular Dextrose prolotherapy for pain relief in knee O.A.

Protocol summary

Summary

The main objective of the study, to compare the effect of periarticular versus intraarticular injection for pain of knee osteoarthritis. In a double-blind randomized clinical trial, 104 patients with knee pain for at least 3 months (who have not responded adequately to conservative treatment) and in accordance with the inclusion and exclusion criteria, were enrolled. Patients were randomly divided to two groups. In group I, 8 ml of Dextrose 10% + lidocaine 1% was injected (inside the knee joint) through the infra patellar approach by a 23 G needle. Injections were repeated at 1 and 2 weeks after the first injections. In group II, 10 ml of Dextrose 10% + lidocaine 1% was injected subcutaneously at 4 points of periarticular area around the knee. The injections were performed fan wise by 2.5 ml of drug at each point with a 23G needle. Injections were repeated at 1 and 2 weeks after the first injections. After injections, patients were scheduled for follow up at 1, 2 and 3 months after the first injections. Pain-scale was measured with using visual analogue scale (VAS) (0-100), and disability index was measured with using Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, flexion range of motion and patient satisfaction were measured, at each visit. All pain killers were discontinued at 48 hours before of the procedure to 2 weeks after that (Except acetaminophen). Physician injecting drug and the one evaluating patients in follow-up were different and were blind to patients group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102713364N3**

Registration date: **2016-11-02, 1395/08/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-02, 1395/08/12

Registrant information

Name

Mehrdad Taheri

Name of organization / entity

Shahid Beheshti University of Medical Science

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Shahid Beheshti University Of Medical Sciences, Tehran, Iran.

Expected recruitment start date

2015-04-20, 1394/01/31

Expected recruitment end date

2016-01-15, 1394/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of periarticular & intrarticular Dextrose prolotherapy for pain relief in knee O.A.

Public title

Dextrose effect in the treatment of pain in osteoarthritis of the knee

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with chronic osteoarthritis; age over 50 years; grade 2 or higher of OA in radiology; morning stiffness less than 30 minutes; 3 month unresponsiveness to conservative therapy.

Exclusion criteria: severe underlying disease; coagulopathy; history of rheumatologic disorders; diabetes; history of corticosteroid therapy in past year; history of prolotherapy in past year; history of intraarticular injection in past year; indication for surgical arthroplasty.

Age

From **50 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **104**

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

Vice Chancellor for Research and Technology of Shahid Beheshti University Of Medical Sciences

Street address

shahid Abbas Arabi Street, yemen Street, Shahid Chamran highway, Shahid Beheshti University Of Medical Sciences

City

Tehran

Postal code

Approval date

2015-10-18, 1394/07/26

Ethics committee reference number

ir.sbm.u.ram.rec.1394.297

Health conditions studied

1

Description of health condition studied

Gonarthrosis [arthrosis of knee]

ICD-10 code

M17.0

ICD-10 code description

Primary gonarthrosis, bilateral

Primary outcomes

1

Description

pain

Timepoint

Each month for 3 months

Method of measurement

VAS

2

Description

WOMAC Index

Timepoint

Each month for 3 months

Method of measurement

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Secondary outcomes

1

Description

Patient satisfaction

Timepoint

Each month for 3 months

Method of measurement

0 = absolutely no pain, 1 = sometimes moderate pain, 2 = moderate pain ever 3 = Only sometimes severe pain, 4 = always moderate pain and sometimes severe pain 5 = Always sharp pain

Intervention groups

1

Description

In group I, 8 ml of Dextrose 10% + lidocaine 1% were injected (inside the knee joint) through an infra patellar approach by a 23 G needle. Injection was repeated at 1 and 2 weeks after first injection.

Category

Treatment - Other

2

Description

In group II, 10 ml of Dextrose 10% + lidocaine 1% was injected subcutaneously at 4 points of periarticular area around the knee. The injection was performed fan wise by

2.5 ml of drug at each point with an 23G needle.
Injections were repeated at 1 and 2 weeks after first injection.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital's pain clinic

Full name of responsible person

Mehrdad Taheri

Street address

Shahid Madani street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of
Shahid Beheshti University Of Medical Sciences

Full name of responsible person

Mostafa Alavimoghaddam

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shahid Abbas Arabi Street, yemen Street, Shahid
Chamran highway, Shahid Beheshti University Of
Medical Sciences

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research and Technology of Shahid
Beheshti University Of Medical Sciences

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mehrdad Taheri

Position

Assistant Professor

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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