

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of different concentrations of dextrose in prolotherapy on relieving knee osteoarthritis pain

Protocol summary

Study aim

Finding the best concentration of hypertonic dextrose in knee prolotherapy

Design

Clinical trial in three group without control group, parallel groups, double blinded with blinded outcome assessment, randomised, on 93 patients, for randomisation used blocked randomisation

Settings and conduct

This study evaluate the effects of different concentrations of hypertonic dextrose in 93 patients with knee osteoarthritis in sanandaj city. Patients categories in three randomised group that receive three times hypertonic dextrose injection in eight point of their knee and evaluate 1,3 and 6 month after injection. Patient, procedure performer and who evaluate are blinded about patient's group.

Participants/Inclusion and exclusion criteria

Patients with knee osteoarthritis diagnosed, with pain and at least three of this six criteria :age more than 50 years, morning stiffness less than 30 minutes, cripitation in active knee moving, bone sensitivity, bone enlarged, no warming in joint feeling. Criteria for reject: stroid drugs injection in last two weeks, diabetes mellitus, candidates for surgery (stiffness grade four), history of dextrose injection, knee infection in last three mounts, daily opium use, history of inflammatory arthritis, heridatory or traumatic bone dissformation, vascular necrosis, body mass index more than 30.

Intervention groups

In three randomised choosen group, in eight locality of anterior and posterior of knee injection performing based on their groups, three times with two weeks distance

Main outcome variables

pain; knee stiffness and structural function; physical movement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201214049707N1**

Registration date: **2021-04-19, 1400/01/30**

Registration timing: **prospective**

Last update: **2021-04-19, 1400/01/30**

Update count: **0**

Registration date

2021-04-19, 1400/01/30

Registrant information

Name

Saeid Biglary

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3362 8194

Email address

saeid.biglary@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of different concentrations of dextrose in prolotherapy on relieving knee osteoarthritis pain

Public title

the best concentration of injected hypertonic dextrose in knee prolotherapy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

At least three of this six criteria Age more than 50 year's Morning stiffness less than 30 minutes Cripitation in knee moves Bone sensivity Bone enlarged No feeling of arther warming

Exclusion criteria:

Stroid drugs injection in the last two weeks Diabetes mellitus Candidate for knee surgery(degree's of four in stiffness) History of dextrose injection in knees Knee infection in the last three months Knee inflammation Daily opium use History of inflammatory or infected arthritis Heridatory or traumatic injury in knee joint Vascular necrosis Body mass index more than 30

Age

From **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

We use blocked randomisation method. In this method we choose nine paper that writed on three of them H, three M and three L. We mix this nine papers and take one of them for every patient randomly and categories them acording to their paper

Blinding (investigator's opinion)

Triple blinded

Blinding description

In time of procedure, patient and performer are blind about patient's category and individual that receive and write affect of procedure is blind too.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of kurdistan university of medical sciences

Street address

No.4,Khane Aftab Building, Tahmasebi street, Shark Saade phase 2, Sanandaj

City

SANANDAJ

Province

Kurdistan

Postal code

6617953775

Approval date

2021-03-17, 1399/12/27

Ethics committee reference number

IR.MUK.REC.1399.327

Health conditions studied**1****Description of health condition studied**

Knee Osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes**1****Description**

Severity of pain is the most important item that is affected on disability of patients with knee osteoarthritis and in this research through the WOMAC score evaluate before and after the procedure.

Timepoint

Before intervention, one, three and six months after the first injection

Method of measurement

Via questionnaire that designed for this research plus WOMAC score questionnaire

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

Severity of the pain is the most important item and the most affected on patient's disability that evaluates. Morning stiffness is a limiter cause that evaluates. Restriction for daily activities will evaluates.

Timepoint

Before intervention, one, three and six months after the first injection

Method of measurement

Via WOMAC score questionnaire

Intervention groups

1

Description

Intervention group: first group : 16 millilitres of Dextrose 15 % plus 4 millilitres of lidocaine 2 %, inject in four points in the anterior and four points in the posterior of knee. This will be repeat two times with distance of two weeks.

Category

Treatment - Drugs

2

Description

Intervention group: Second group :16 millilitres of Dextrose 30% plus 4 millilitres of lidocaine 2 %, inject in four points in the anterior and four points in the posterior of knee. This will be repeat two times with distance of two weeks.

Category

Treatment - Drugs

3

Description

Intervention group: Third group 16 millilitres of Dextrose 50 % plus 4 millilitres of lidocaine 2 %, inject in four points in the anterior and four points in the posterior of knee. This will be repeat two times with distance of two weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kousar hospital

Full name of responsible person

Saeid Biglary

Street address

Fatehy nahid square, Pasdarn Blvd, kousar hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Dr.Karim Naseri

Street address

Medical school, Pasdaran Blvd,

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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

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Saeid Biglary

Position

Assistant of anesthesia

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

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

The major information of patient's chronic disease, risk factors and kind of the intervention are capable for publication after doing unrecognisable patient's identity

When the data will become available and for how long

One to three months after presentation and print the consequences in origin university

To whom data/document is available

All researchers and Co_workers in medical field

Under which criteria data/document could be used

Use of this research and deployment that is possible for researchers and those who have speciality and licence in medical field.

From where data/document is obtainable

Dsbiglary@gmail.com No: 00989183715979

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

Applying for above addresses and presentation documents for authentication and obligation for taking necessary and legal licenses

Comments