# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jul 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 afect 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 Bvld, kousar hospital
**City**
Sanandaj
**Province**
Kurdistan
**Postal code**
16679588
**Phone**
+98 87 3361 1309
**Email**
Dsbiglary@gmail.com

## 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,
**City**
Sanandaj
**Province**
Kurdistan
**Postal code**
6616545
**Email**
Dsbiglary@gmail.com
**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
**Street address**
No.4,Khane Aftab,Tahmasebi street, Shark Saadi , phase 2, Sanandaj
**City**
Sanandaj
**Province**
Kurdistan
**Postal code**
6617953775
**Phone**
+98 87 3362 8194

**Fax**

**Email**
Saeid.Biglary@muk.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Sanandaj University of Medical Sciences

**Full name of responsible person**
Saeid Biglary

**Position**
Assistant of anesthesiology

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Anesthesiology

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

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**Postal code**
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**Phone**
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**Fax**

**Email**
Saeid.Biglary@muk.ac.ir

## Person responsible for updating data

**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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**Fax**

**Email**
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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**