Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of the effect of peri-articular injection of dextrose and corticosteroid with dextrose alone on pain relief in patients with knee osteoarthritis.

Protocol summary

Study aim
Comparison of the effect of periarticular injection of dextrose, corticosteroids and their combination on pain relief in patients with knee osteoarthritis

Design
The clinical trial has an intervention and control parallel groups, single blinded, randomized with blocking, phase 3, on 40 patients.

Settings and conduct
One-blind and interventional study with dextrose injection and dextrose with steroid on 40 patients with OA will be performed in the rheumatology clinic of Tohid Hospital in Sanandaj.

Participants/Inclusion and exclusion criteria
Inclusion criteria: There are at least three of ACR criteria ,evidence for osteoarthritis on radiography or based on the Kellgren-Lawrence index.Exclusion criteria:Any use of painkillers or previous injections in the joint and all systemic diseases involving the joint and obesity

Intervention groups
In the dextrose group, 0.5cc dextrose 20% in combination with 0.5cc 2% lidocaine and in the control group a single dose of 40mg methylprednisolone acetate (0.5 cc) in combination with 0.5cc 2% lidocaine with 0.5cc dextrose 20% In combination with 0.5 cc of 2% lidocaine, an injection will be given in the peri-articular area of both legs and patients will be followed up for up to three months.

Main outcome variables
Changes of pain, knee stiffness and physical function using a questionnaire (WOMAC)

General information

Reason for update
Acronym
IRCT registration information

IRCT registration number: **IRCT20210930052641N1**
Registration date: **2022-01-20, 1400/10/30**
Registration timing: **prospective**

Last update: **2022-01-20, 1400/10/30**
Update count: **0**

Registration date
2022-01-20, 1400/10/30

Registrant information
Name
Nasrin Moghimi
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-01-21, 1400/11/01
Expected recruitment end date
2022-05-22, 1401/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of peri-articular injection of dextrose and corticosteroid with dextrose alone on pain relief in patients with knee osteoarthritis.

Public title
Comparison of the effect of peri-articular injection of dextrose and corticosteroid with dextrose alone on pain relief in patients with knee osteoarthritis.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Existence of at least three of the six ACR criteria: 1. Age over 50 years, 2. Morning stiffness less than 30 minutes, 3. Cryptation sensation in active knee movements, 4. Bone sensitivity, 5. Bone enlargement, 6. Absence of warmness at the touch of the joint Evidence for osteoarthritis on knees radiography Grade 2 or 3 osteoarthritis based on the Kellgren-Lawrence index
Exclusion criteria:
Previous therapeutic injection with dextrose Use of braces or NSAIDs or daily use of opioids during the study Pregnancy, Lactation Contraindication to corticosteroid injection History of metabolic bone disease, coagulation disorders Injection of steroid drugs in the last 2 months History of joint fracture History of inflammatory joint disease, post-infection arthritis, joint dysplasia, congenital anomalies, crystallopathy, post-traumatic arthritis, malignancy, vascular necrosis Obesity BMI>30 Knee infection in the last three months or knee inflammation Candidate patients for knee surgery Diabetes
Age
From **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **1**
Each person receives one type of intervention
Randomization (investigator's opinion)
Randomized
Randomization description
The sample will be randomly divided into 2 groups so that the patients with the condition are assigned as a double block (AB) by the researcher based on the random allocation table. Then a package containing 40 cards with one of the letters A and B (20 each), It is considered to randomly select a card from the package and enter one of the groups according to the Latin letter. Sampling is done in parallel in 2 groups until the number of samples is completed. It is then randomly divided into two groups receiving 20% dextrose alone and 20% dextrose with corticosteroid.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, patients are aware of receiving the drug to each of the intervention and control groups, but do not know to which intervention and control group they were randomly assigned.
Placebo
Not used
Assignment
Parallel
Other design features
none

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kurdistan University of Medical Sciences
Street address
Department of Internal Medicine, School of Medicine, Kurdistan University of Medical Sciences, Sanandaj, Iran
City
Sanandaj
Province
Kurdistan
Postal code
6616813131
Approval date
2021-11-17, 1400/08/26
Ethics committee reference number
IR.MUK.REC.1400.211

Health conditions studied

1

Description of health condition studied
Osteoarthritis
ICD-10 code
M19.91
ICD-10 code description
Primary osteoarthritis, unspecified site

Primary outcomes

1

Description
Pain
Timepoint
Before intervention , 1 month after one intervention and 3 months after one intervention
Method of measurement
using questionnaire (Western Ontario & McMaster Universities Osteoarthritis Index)

2

Description
Knee fatigue
Timepoint
Before intervention , 1 month after one intervention and 3 months after one intervention
Method of measurement
using questionnaire (Western Ontario & McMaster Universities Osteoarthritis Index)

3

Description
Physical function
Timepoint
Before intervention , 1 month after one intervention and 3 months after one intervention
Method of measurement
using questionnaire (Western Ontario & McMaster Universities Osteoarthritis Index)

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group (group receiving 20% dextrose alone), both legs will be injected into the periarticular area. Dextrose 0.5 cc Dextrose 20% in combination with 0.5 cc lidocaine 2% injection will be performed in the periarticular area.
Category
Treatment - Drugs

2

Description
In the control group (group receiving 20% dextrose with corticosteroids), a single dose of 40 mg methylprednisolone acetate (0.5 cc) in combination with 0.5 cc of 2% lidocaine with 0.5 cc of 20% dextrose in combination with 0.5 CC lidocaine 2% injection is performed in the periarticular area and patients will be followed up for up to three months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tohid Hospital of Sanandaj
Full name of responsible person
Shirin Nourbakhsh
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Department of Internal Medicine, School of Medicine, Kurdistan University of Medical Sciences, Sanandaj, Iran
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Sponsors / Funding sources

1

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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
Shirin Nourbakhsh

Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information.
Study Protocol
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable