Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of therapeutic effect of corticosteroid injection with hypertonic dextrose in patients with knee osteoarthritis

Protocol summary

Study aim
Determination of the therapeutic effect of corticosteroid injection in comparison with injection of hypertonic dextrose in patients with knee osteoarthritis

Design
Random sampling,convenience sampling and then patients will be assigned to two groups by block randomization.The study is double blind (patients and analyzer sample size:48

Settings and conduct
Patients with knee osteoarthritis referred to physical medicine clinics (iran university of medical sciences). Patients are randomly divided into two groups in closed packaging.

Participants/Inclusion and exclusion criteria
The main inclusion criteria: Patients with Knee Osteoarthritis Based on American College of Rheumatology Criteria 2 and 3 in accordance with Lowrence Criteria - Kellergan, Knee pain for at least six months,Age 40 to 75 years, absence of any acute or chronic infection, Pregnancy or no pregnancy decision,Failure to perform any intra-articular injection of the knee during the past three months,absence of inflammatory arthritis or secondary osteoarthritis, No history of knee surgery, Not having a severe underlying disease such as uncontrolled diabetes, taking anti-coagulants, Not taking opioid and non-opioid analgesics daily

Intervention groups
Under sterile conditions, in one group of patients 40 mg triamcinolone is injected via suprapetellar patch into the knee joint (in one session) and in another group of patients, 5cc dextrose hypertonic 20% is injected through the supra patellar patch into the knee joint.

Main outcome variables
outcomes: Before injection, patients' pain severity, WOMAC score, and clinical evaluation (range of motion) will be determined in both groups of patients, and these criteria will be assessed one week, one month, and three months after injection.The results will be compared before and after injection in each group and between the two groups.

General information

Reason for update
Correction of sampling date

Acronym

IRCT registration information
IRCT registration number: **IRCT20191002044951N1**
Registration date: **2019-11-04, 1398/08/13**
Registration timing: **prospective**

Last update: **2020-07-04, 1399/04/14**
Update count: **1**

Registration date
2019-11-04, 1398/08/13

Registrant information

Name
Koorosh Mansoori

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-05, 1398/08/14

Expected recruitment end date
2019-12-05, 1398/09/14

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of therapeutic effect of corticosteroid injection with hypertonic dextrose in patients with knee osteoarthritis

Public title
Comparison of the therapeutic effect of corticosteroid injection with hypertonic dextrose in patients with knee osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All knee osteoarthritis patients with Grade 1 and 2 All knee osteoarthritis patients between the ages of 1 and 2 years
Exclusion criteria:
Age less than 2 years and more than 5 years Osteoarthritis with Grade 1 and 2 Pregnancy Severe underlying disease
Age
From **40 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization, in which each member of the community has an equal chance of being independent, is chosen. The randomization method will be used with random and binary blocks. Regarding the sample size of 54 people, 13 quadruple blocks and 1 binary block will be generated and numbered using the permutations method. Using the random number table , blocks will be placed together to form a patient allocation sequence to treatment groups. Providers will be unaware of the type of treatment that will be received, as well as the random sequences generated in The length of the study will be unpredictable.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients and analyzers are unaware of the drugs given to the control and intervention groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Valiasr Square, Behafarin Street, Firoozgar Hospital
City
Tehran
Province
Tehran
Postal code
1593747811
Approval date
2019-01-15, 1397/10/25
Ethics committee reference number
IR.IUMS.FMD.REC.1397.226

Health conditions studied

1

Description of health condition studied
Knee Osteoarthritis
ICD-10 code
M17.0
ICD-10 code description
Bilateral primary osteoarthritis of knee

Primary outcomes

1

Description
The severity of pain
Timepoint
Zero,one week,one month and three month after
Method of measurement
Visual Analog Scale(VAS)

2

Description
The severity of symptoms and functional limitations
Timepoint
Zero,one week,one month and three month after
Method of measurement
WOMAK questionnaire

3

Description
Range of motion
Timepoint
Zero,one week,one month and three month after

Method of measurement
Goniometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1 : Under sterile conditions, 5cc dextrose hypertonic 20% is injected into the knee joint through the supra peltar patch.Injection with 25 gage needle is performed . Before injection, pain severity and WOMAC score and clinical evaluation (ROM) were determined in both groups of patients and these criteria were evaluated one week, one month and three months after injection.
Category
Treatment - Drugs

2

Description
Intervention group 2: Under sterile conditions, 40 mg triamcinolone is injected via suprapetellar patch into the knee joint (in one session).Injection with 25 gage needle is performed . Before injection, pain severity and WOMAC score and clinical evaluation (ROM) were determined in both groups of patients and these criteria were evaluated one week, one month and three months after injection.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
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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
Iran 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
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Resident of physical and rehabilitation
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available