

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 Lowrance 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 suprapatellar 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

Country

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

AgeFrom **40 years** old to **75 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget 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**

Firoozgar Hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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**

Iran University of Medical Sciences

Full name of responsible person

Forugh Zarnegar

Position

Resident of physical and rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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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