Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparisonof the effectiveness of intra-articular injection of hypertonic saline, intra-articular injection of HIALGAN and knee physiotherapy in pain and function of patients with knee osteoarthritis

Protocol summary

Study aim

Comparison of the effect of intra-articular injection of hypertonic saline and HIALGAN and knee physiotherapy on pain (with Visual analog state(VAS)) and performance (with Knee injury and Osteoarthritis Outcome Score(KOOS)) in knee osteoarthritis patients Implementation of a uncomplicated and low-cost treatment for knee osteoarthritis

Design

Phase 3 clinical trial , with two intervention groups and one control group in parallel, one blind, randomized with blocks 3 or 6 , with 90 sample

Settings and conduct

The patients who come to the Physical Medicine Clinic of Imam Reza Hospital. Main variables analysis before, 1 month, 3 months and 6 months after treatment The researcher, outcome evaluator, and data analyzer are blinded by assigning code to each patient, depending on the group being treated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with knee pain and dysfunction who have the American College of Rheumatology criteria and whose illness is subacute or chronic. Patients with secondary arthritis or diseases that affect the joints and muscles are excluded. Patients who have had joint replacement or recent intra-articular injections are excluded from the study.

Intervention groups

1.The patient undergoing intra-articular injection of 5 mililiter Hypertonic saline, 5%, at one time. 2. The patient undergoes HYALGAN intra-articular injection three times 3. The patient undergoes knee physiotherapy (IR, TENS, US (Palsed)) in 10 sessions. For all patients, acetaminophen 500 mg tablets are prescribed for use in the event of pain.Strengthening exercises of quadriceps, hip abductor and hip adductor muscle groups , and hamstring stretching exercises, are prescribed.

Main outcome variables

Pain severity based on VAS score Severity of symptoms of osteoarthritis, severity of pain, severity of daily activities, joint stiffness and quality of life based on KOOS criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190309042989N1**
Registration date: **2019-04-19, 1398/01/30**
Registration timing: **prospective**

Last update: **2019-04-19, 1398/01/30**
Update count: **0**

Registration date

2019-04-19, 1398/01/30

Registrant information

Name

Ensieh Taftian

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-05, 1398/02/15

Expected recruitment end date

2019-12-06, 1398/09/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparisonof the effectiveness of intra-articular injection of hypertonic saline, intra-articular injection of HIALGAN and knee physiotherapy in pain and function of patients with knee osteoarthritis

Public title
Comparison of the effect of intra-articular hypertonic saline, intra-articular HIALGAN and physiotherapy in patients with knee arthritis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
ACR criteria (age more than 50 years old / cryptasion or morning stiffness less than 30 minutes / presence of radiographic evidence / presence of symptoms for more than three months) K-L radiographic criteria : grade 2-4
Exclusion criteria:
Patient dissatisfaction Other joint arthritis in the knee joint including rheumatoid arthritis and gout or systemic neuromuscular disorders such as Myasthenia Gravis, Eton-Lambert syndrome and ALS. History of total Knee arthroplasty History of fracture in the knee bones Intra-articular corticosteroid injection over the past 2 weeks, history of hyaluronic acid injection or proletherapy over the past one year Any contraindication for intra-articular injection such as thrombocytopenia , coagulation disorder, joint infections, skin infections at the injection site Dysfunction of the lower extremity due to neurological or internal diseases such as stroke, traumatic brain injury, and diabetic foot disease Severe knee joint effusion BM I> 35 Acute exacerbation of knee pain (less than 1 month)
Age
From **50 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
More than 1 sample in each individual
Number of samples in each individual: **2**
In patients, depending on the symptom and pain of patients, one or both knees is treated ,The number of samples is the same number of knees treated.
Randomization (investigator's opinion)
Randomized
Randomization description
Patients with knee osteoarthritis will be recruited from the waiting list of an outpatient Department of Physical Medicine and Rehabilitation at Imam Reza Hospital. The Hospital is a large referral subspecialty center in Tehran affiliated with Artesh University of Medical Sciences. We are going to use block randomization with variable block size to provide four samples of equal size and patients are assigned to one of the arms using random blocks (90 samples are included in the study and divided into 3 groups with equal number, the first group :30 samples underwent intra-articular injection of hyper-saline, the second group : 30 samples underwent HYALGAN intra-articular injection and the third group: 30 samples underwent 10-session physiotherapy.). Random numbers will be generated with a computer in an independent statistical office.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to different treatments and the number of different treatment sessions in each patient group, the patients and physician(was responsible to prescribing and explaining the treatment) was not blinded . The person responsible for evaluating the patients with the pre and post questionnaire (who was the main researcher) had no information on the treatment process and the patient group, so that the questionnaire was completed before the determination of the treatment method and after beginning of the treatment, every questionnaire depending on treatment method, a code (1. 2 or 3) is assigned and was in charge for re-evaluation. After completion of the questionnaires, it is available to the data analyst and analyzed using the same allocation code to each data group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Artesh University of Medical Sciences
Street address
Emam Reza Hospital , Etemadzade Ave. , West Fametemi Blvd.
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Tehran
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Postal code
1411718541
Approval date

2019-04-13, 1398/01/24

Ethics committee reference number

IR.AJAUMS.REC.1398.003

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

Pain intensity based on the Visual Analogue Scale

Timepoint

Measuring pain intensity before the intervention, 1 month, 3 months and 6 months after the end of the intervention.

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Symptoms

Timepoint

Before the intervention, 1 month, 3 months and 6 months after the end of the intervention

Method of measurement

Knee injury and Osteoarthritis Outcome Score (KOOS)

2

Description

Pain

Timepoint

Before the intervention, 1 month, 3 months and 6 months after the end of the intervention

Method of measurement

Knee injury and Osteoarthritis Outcome Score (KOOS)

3

Description

Function, daily living

Timepoint

Before the intervention, 1 month, 3 months and 6 months after the end of the intervention

Method of measurement

Knee injury and Osteoarthritis Outcome Score (KOOS)

4

Description

Function, sports and recreational activities

Timepoint

Before the intervention, 1 month, 3 months and 6 months after the end of the intervention

Method of measurement

Knee injury and Osteoarthritis Outcome Score (KOOS)

5

Description

Quality of Life

Timepoint

Before the intervention, 1 month, 3 months and 6 months after the end of the intervention

Method of measurement

Knee injury and Osteoarthritis Outcome Score (KOOS)

Intervention groups

1

Description

First intervention group: Intra-articular injection of 5cc from Hypertonic Saline solution 5%(solution with a concentration of sodium chloride) at one time .Hypersalin brand medication from Shahid Ghazi pharmaceutical company. The method of intra-articular injection of the knee is determined according to the common methods and the amount of access to joint space in the plane radiography (inferomedial or medial, lateral approach). Prescribing 500 mg acetaminophen for use in pain situations and prescribing strengthening exercise for Quadriceps, hip adductors and hip abductors and stretching exercise for calf and hamstring muscles.

Category

Treatment - Drugs

2

Description

Second intervention group: intra-articular injection of 2 cc from HYALGAN (Pre-filled syringe for intra-articular use , contain 20 milligram Hyaluronic acid sodium salt, with 2 miligram volume, From Fidia-Italy pharmaceutical company)inject 3 times with 1 week interval . The method of intra-articular injection of the knee is determined according to the common methods and the amount of access to joint space in the plane radiography (inferomedial or medial, lateral approach) .Prescribing 500 mg acetaminophen for use in pain situations and prescribing strengthening exercise for Quadriceps, hip adductors and hip abductors and stretching exercise for calf and hamstring muscles.

Category

Treatment - Drugs

3

Description

Control group: Knee physiotherapy involves using an

infrared device for 20 minutes at a distance of 1 m from the body and perpendicularly, using a transcutaneous electrical nerve stimulation (TENS) device for 20 minutes (with a high TENS protocol that includes a frequency of 100 to 150 Hz , A pulse duration of 150 microseconds and at tolerance level) and the use of an ultrasound device for 3 to 5 minutes (1 MHz frequency, 1.5 Watts per square centimeter and palsed protocol).Prescribing 500 mg acetaminophen for use in pain situations and prescribing strengthening exercise for Quadriceps, hip adductors and hip abductors and stretching exercise for calf and hamstring muscles.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

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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
Artesh 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
Artesh University of Medical Sciences
Full name of responsible person
Dr. Ensieh Taftian
Position
Resident
Latest degree
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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