

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Hyaluronic Acid Compared with Corticosteroid Injections for the Treatment of Osteoarthritis of the knee

Protocol summary

Summary

This randomized, double blind, parallel study was conducted with 140 knee OA patient to compare the Therapeutic effects of corticosteroids and hyaluronic acid. Patients will visit by a physician . after they signed informed consent they will choose. individuals randomly divided into two groups. Intensity of pain will assess by Visual analogue scale and Western Ontario McMaster University Osteoarthritis questionnaire. The treatment consisted of one IA injections of HA or one injections of CS and the follow-up visits were scheduled at 1 months, 2 months, and 3 months Qualified patients were men and women from 45 years to 80 years of age suffering from knee OA for more than 3 months, with radiographic. Main exclusion criteria was The use of NSAIDs in 2 days prior to injection. Patients and investigators were blinded in this study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015031421460N1**

Registration date: **2015-08-01, 1394/05/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-01, 1394/05/10

Registrant information

Name

Tahereh Gholami

Name of organization / entity

Fasa University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Fasa University of Medical Sciences

Expected recruitment start date

2015-05-05, 1394/02/15

Expected recruitment end date

2015-06-05, 1394/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Hyaluronic Acid Compared with Corticosteroid Injections for the Treatment of Osteoarthritis of the knee

Public title

Hyaluronic Acid Compared with Corticosteroid Injections for the Treatment of Osteoarthritis of the knee

Purpose

Treatment

Inclusion/Exclusion criteria

Qualified patients were men and women from 45 years to 80 years of age suffering from knee OA for more than 3 months, with radiographic. Main exclusion criteria were a history or presence of trauma or surgery or cancer or malignant tumors, infections and sores on the target knee, History of vasovagal shock , The use of NSAIDs in 2 days prior to injection, Any receiving corticosteroids injection in the knee in the last 6 months , Pregnancy and lactation

Age

From **48 years** old to **13 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Fasa University of Medical Sciences

Street address

Fasa University of Medical Sciences, Ebne Sina square, Fasa, Fars

City

Fasa

Postal code

Approval date

2014-12-02, 1393/09/11

Ethics committee reference number

e- 9306

Health conditions studied

1

Description of health condition studied

Knee Osteoarthritis

ICD-10 code

M17- M18-

ICD-10 code description

Gonarthrosis [arthrosis of knee]

Primary outcomes

1

Description

pain

Timepoint

before intervention- one- two- three months after intervention

Method of measurement

Visual analogue scale and questionnaire

Secondary outcomes

1

Description

Physical function

Timepoint

before and after intervention

Method of measurement

questionnaire and interview with patients

Intervention groups

1

Description

Patients participating in the study will be divided into two groups of 70 people. One group will take 40 mg Depomedrol corticosteroid injection in the space between the knee joint by an orthopedic physician. And second group will take hyaluronic acid (Hyalgan) in 2 ml vials to the space between the knee joint by an orthopedic physician.

Category

Treatment - Drugs

2

Description

intervention group: hyaluronic acid (Hyalgan) in 2 ml vials to the space between the knee joint by an orthopedic physician

Category

Treatment - Drugs

3

Description

control group: this group will take 40 mg Depomedrol corticosteroid injection in the space between the knee joint by an orthopedic physician

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamzeh hospital/ Fasa University of Medical Sciences

Full name of responsible person

Tahereh Gholami

Street address

Fasa University of Medical Sciences

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Fasa University of Medical Sciences

Full name of responsible person

Dr. Ehsan Bahramali

Street address

Fasa University of Medical Sciences, Ebne Sina square, Fasa, Fars

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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

Vice Chancellor for research of Fasa University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Dr. Alireza Askari

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

