Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating and comparing the efficacy of treatment with chondroitin sulfate and hyaluronic acid in patients with knee osteoarthritis

Protocol summary

Study aim
The complications of the drugs used in osteoarthritis have led the researchers to use chondroitin sulfate and hyaluronic acid in patients with knee osteoarthritis and to evaluate and compare the effectiveness of treatment with chondroitin sulfate and hyaluronic acid in patients with knee osteoarthritis Pay attention

Design
Clinical trials with control group, one blind

Settings and conduct
Ayatollah Mousavi Hospital in Zanjan

Participants/Inclusion and exclusion criteria
Entry requirements: Patients with knee osteoarthritis with clinical and para-clinical diagnostic criteria
Conditions of non-arrival: patient dissatisfaction؛ hypersensitivity to hyaluronic acid؛ localized skin infection ؛unilateral DJD

Intervention groups
For each patient, both drugs (chondroitin sulfate-hyaluronic acid) injected into the right knee and hyaluronic acid were injected into the left knee. Then, in four, one month, three months, six months and nine months, clinical symptoms including pain, joint dryness and distance traveled through the checklist were evaluated.

Main outcome variables
Pain; joint range of motion; distance traveled

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190226042854N1**
Registration date: **2019-03-17, 1397/12/26**
Registration timing: **retrospective**

Last update: **2019-03-17, 1397/12/26**
Update count: **0**

Registration date
2019-03-17, 1397/12/26

Registrant information

Name
Asghar Abedi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3741 2698

Email address
asghar.abedi71@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-21, 1397/02/01

Expected recruitment end date
2019-01-21, 1397/11/01

Actual recruitment start date
2018-04-21, 1397/02/01

Actual recruitment end date
2019-01-21, 1397/11/01

Trial completion date
2019-02-20, 1397/12/01

Scientific title
Evaluating and comparing the efficacy of treatment with chondroitin sulfate and hyaluronic acid in patients with knee osteoarthritis

Public title
The effect of arthromac plus in the treatment of knee arthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with knee osteoarthritis with clinical and para-clinical diagnostic keratitis suffer from bilateral knee osteoarthritis.

Exclusion criteria:

No patient satisfaction Hyaluronic acid hypersensitivity Local skin infection Unilateral DJD

Age

From **50 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **54**

More than 1 sample in each individual

Number of samples in each individual: **2**

The patient's left and right knees

Actual sample size reached: **54**

More than 1 sample in each individual

Actual sample size in each individual: **2**

The patient's left and right knees

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

A complete explanation was given to the patient about studying and comparing the therapeutic effect of drugs. The patient then received both ampoule arthromac plus (hyaluronic acid-chondrotin sulfate) and arthromac (hyaluronic acid). Then arthromac Plus was injected in the right knee and arthromac in the left knee. The patient did not have any information about the type of injectable drug in his knees. The appearance of both ampoules was identical (milky). During the study, only a physician was aware of the type of injected drug on the knees and information was collected by the same physician. The other person, including the patient himself and the nurse and the medical staff, did not know the type of injected drug on the knees.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zanjan University of Medical Sciences

Street address

Specialized and Specialized Training Center of Ayatollah Mousavi, Gavazang Road

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2018-04-14, 1397/01/25

Ethics committee reference number

IR.ZUMS.REC.1397.174

Health conditions studied

1

Description of health condition studied

Osteoarthritis

ICD-10 code

M19.9

ICD-10 code description

Osteoarthritis, unspecified site

Primary outcomes

1

Description

Pain score in patients after drug injection based on VAS

Timepoint

1 month, 3 months, 6 months, 9 months

Method of measurement

questionnaire

Secondary outcomes

1

Description

Pain; Range of motion ; distance traveled

Timepoint

1 month, 3 months, 6 months, 9 months

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Patient right knee; In this group injections of intravenous injection of Arthromc plus, containing 3 ml of hyaluronic acid-chondrocyte sulfate, at a concentration of 20 MG / ML, made in France, NOVATEX BIOENGINEERING.

Category

Treatment - Drugs

2

Description
Control group: The left knee was injected intradermally. In this group, the injection of intravenous injection of artrocomic ampoule containing 3 ml of hyaluronic acid at a concentration of 20 MG / ml, made in France, NOVATEX BIOENGINEERING.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Mousavi Hospital in Zanjan

Full name of responsible person
Asghar Abedi

Street address
mousavi hospital - gavazang road - zanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Dr.Alireza Shoghli

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mousavi hospital - gavazang road - zanjan

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Zanjan 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
Zanjan University of Medical Sciences

Full name of responsible person
asghar abedi

Position
دانشجوی پزشکی

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Aban Complex, Azadegan Town

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Aghar Abedi

Position
medical student

Latest degree
Medical doctor

Other areas of specialty/work
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Person responsible for updating data

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Position

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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