Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 2026

Comparative evalution of the effect L. Cream (containing Elaeagnus angustifolia extract) and Tab diclofenac on the clinical symptoms of knee osteoarthritis patients: A Randomized, Double-Blind, Equivalence Trial

Protocol summary

Study aim
Comparison of the effect of prescribing elderberry gel (L. cream: containing elderberry fruit extract) with diclofenac tablets on the clinical symptoms of patients with knee osteoarthritis

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 112 patients, simple block randomization is used for randomization.

Settings and conduct
This clinical trial is a double-blind randomized trial and is conducted on eligible knee osteoarthritis patients at the rheumatology clinic of Sayad Shirazi Educational-Therapeutic Center, Gorgan. groups are categorized, diclofenac tablets are obtained from the pharmaceutical market, and elderberry gel placebo is produced with an appearance completely similar to elderberry gel, and it is provided to research samples based on random codes. In this study, the researcher and subjects The study subject will not know the contents of the packages.

Participants/Inclusion and exclusion criteria
Entry conditions: Osteoarthritis knee patients aged 40 to 75 years of both sexes with non-traumatic knee pain in the last 6 months who were graded II and III according to the K_L scale in radiography. Conditions of non-entry: patients with a history of joint damage, uncontrolled blood pressure, osteo-articular diseases (diabetic, rheumatism, osteonecrosis and gout).

Intervention groups
Group A patients receive "treatment with diclofenac tablets plus elderberry gel" for 8 weeks. Group B patients receive "treatment with diclofenac tablets plus placebo elderberry gel" for 8 weeks.

Main outcome variables
Score Questionnaire WOMAC (Western Ontario and Universities Osteoarthritis Index)

General information

Reason for update

Acronym
L.c

IRCT registration information
IRCT registration number: **IRCT20221212056787N1**
Registration date: **2023-07-19, 1402/04/28**
Registration timing: **prospective**

Last update: **2023-07-19, 1402/04/28**
Update count: **0**

Registration date
2023-07-19, 1402/04/28

Registrant information

Name
hossein alipour

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
2023-09-05, 1402/06/14

Expected recruitment end date
2024-02-03, 1402/11/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparative evalution of the effect L. Cream (containing Elaeagnus angustifolia extract) and Tab diclofenac on the clinical symptoms of knee osteoarthritis patients: A Randomized, Double-Blind, Equivalence Trial

Public title
The effect of Elaeagnus angustifolia gel on knee osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Osteoarthritis patients aged 40 to 75 years of both sexes with non-traumatic knee pain who were graded II and III based on the K-L scale in radiographs of the last 6 months.

Exclusion criteria:
Patients with a history of joint damage, uncontrolled blood pressure, osteoarticular diseases (diabetes, rheumatism, osteonecrosis and gout)

Age
From **40 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **112**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, to minimize the potential bias and increase the reliability of the results, we used block randomization with a size of 4 for two treatment groups. For this purpose, we first specify the number of possible blocks and choose one of the blocks by placing them randomly each time and repeat this process 28 times as follows. BAAB,ABBA,BAAB,AABB,ABBA,AABB,BAAB,BBAA,BABA,BABA,ABAB,BAAB,BBAA,BABA,ABBA,ABAB,BABA,BBAA,BABA,ABAB,BAAB,ABBA,AABB,BAAB,BAAB,BBAA,BBAA,BAAB Based on the order of the letters A and B, the contents of the envelopes are determined in each of the removed blocks so that only one letter is placed in each envelope. The person who delivers the envelopes to the patients does not know the letter inside. Therefore, in addition to the patient, the drug prescriber also does not know how to allocate patients. According to the letter inside the envelope, the patients are placed in the desired group according to the following division.

Blinding (investigator's opinion)
Double blinded

Blinding description
Due to the fact that in each treatment group, a combination of drugs is prescribed in such a way that diclofenac tablets are prescribed together, and also in group 1: elderberry gel, in group 2: placebo, elderberry gel, which leads to the blinding of patients. compared to received interventions. For blinding, we have two groups, Group A: "Diclofenac Tablets plus Elderberry Gel", Group B: "Diclofenac Tablets plus Elderberry Gel Placebo" in this process, Elderberry Gel and Elderberry Gel are similar in appearance.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Golestan University of Medical Sciences

Street address
Central Organization of Golestan University of Medical Sciences and Healthcare Services, Hirkan Boulevard, Gorgan

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Gorgan

Province
Golestan

Postal code
498936316

Approval date
2023-07-11, 1402/04/20

Ethics committee reference number
IR.GOUMS.REC.1402.119

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis

ICD-10 code
M19.9

ICD-10 code description
Osteoarthritis, unspecified site

Primary outcomes

1

Description
Primary outcome: questionnaire score WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index)

Timepoint

At the beginning of the study (before the start of the intervention) and in the fourth and eighth weeks after the treatment with elderberry gel

Method of measurement

questionnaire WOMAC

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group A "Diclofenac 25 mg tablet plus elderberry gel" 2 times a day (Elderberry gel consists of elderberry fruit extract and after being formulated based on Iranian medicine sources, it is made by the researcher of Sepid Gohar Qeshm Company.)

Category

Treatment - Drugs

2

Description

Control group: Group B "Diclofenac 25 mg tablet plus elderberry gel placebo" twice a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayad Shirazi Hospital, Gorgan

Full name of responsible person

Hossein Alipour

Street address

Shahid Sayad Shirazi Blvd, Gorgan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Hossein Alipour

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Information on the main outcome will be shared after de-identification of individuals

When the data will become available and for how long
The access period starts 3 months after the results are published

To whom data/document is available
The data will be available to researchers working in academic and scientific institutions, as well as people working in industry can apply to receive them.

Under which criteria data/document could be used
If researchers, doctors and people working in the pharmaceutical industry want to use Elderberry gel , documents will be given to them.

From where data/document is obtainable
Hossein Alipour-09113222378 alipour209@gmail.com

What processes are involved for a request to access data/document
By sending an e-mail to the given e-mail address and introducing yourself and stating the reason for requesting the documents, after confirming the information sent, the documents will be sent to them

Comments