

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of topical ointment prepared from *Euphorbia macroclada* Boiss on the clinical symptoms of primary knee osteoarthritis

Protocol summary

Study aim

Study of Antiinflammatory ,and Analgesic effects of Farfioun Ointment(EUPHORBIA MACROCLADA)on patients with Osteoarthritis

Design

Assignment of patients to two treatment groups is done by random blocking method, and the obtained sequence is written by one of the colleagues in separate sheets and placed in sealed envelopes, and It will be given to the main researcher to study. In this way, the patient and the evaluating physician and researcher will not know any type of treatment. Data using SPSS software, ANOVA repeated measure test , T test and Chi-square will be analyzed. The sample size is 36 samples.

Settings and conduct

Random blocking; Double Blind Study; Patient_Physician_Researcher; Use www.randomization.com and www.randomizer.org to generate sequences; Special Rheumatology Clinic of Mazandaran University of Medical Sciences _Baghban (Tooba)

Participants/Inclusion and exclusion criteria

Entry requirements: The study population included patients with primary chronic osteoarthritis (grade 1-2); Patients who have not had a joint replacement; Patients 40 to 75 years old; Patients with BMI 26_31. Exclusion criteria: Patients with cognitive impairment or psychiatric disorders will not be included in the study.

Intervention groups

Patients separated to 2 groups by randomization .One group will take standard medicine+farfioun topical ointment(E.M) and the other group will take standard medicine+plasebo.

Main outcome variables

Severity of pain; Rigidity of joint; physical disability.

General information

Reason for update

Due to the fact that during the study, the remarkable results of the Ferfion group were clearly seen. The analysis was done with 41 samples and the difference of the out come indicators in the two groups was significant. Then the study continued by adding 20% to the number of previous samples. And finally The final analysis was done with the number of 50 samples. In fact, due to finding significant statistical and clinical results, in order to comply with ethical considerations, there was no need to continue the study until reaching the number of 72 samples (36 drugs and 36 placebos).

Acronym

IRCT registration information

IRCT registration number: **IRCT20210916052501N1**

Registration date: **2021-11-30, 1400/09/09**

Registration timing: **prospective**

Last update: **2024-02-07, 1402/11/18**

Update count: **1**

Registration date

2021-11-30, 1400/09/09

Registrant information

Name

Faranak Zaker

Name of organization / entity

Incubation center for pharmaceutical technologies,Shaheed Beheshti Medical university

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-04, 1400/09/13

Expected recruitment end date

2022-02-02, 1400/11/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of topical ointment prepared from Euphorbia macroclada Boiss on the clinical symptoms of primary knee osteoarthritis

Public title

Farfioun Effects on Osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients that their Early chronic osteoarthritis are confirmed by romatologist based on Kellgren_Lawrence criteria Early Chronic Osteoarthritis Grade1_2

Exclusion criteria:

Patients with Psychological disorder or Cognitive disorders Patients with sever chronic disorders like insulin-dependent diabetes, Lupus, Kidney disease and patients with uncontrolled hypertension Joint pain because of joint replacement

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

Random blocking; Assignment of patients to two treatment groups is done by random blocking method and in order to produce sequences free website www.randomization.com or randomizer.org is used. The sequence obtained by one of the colleagues is written in separate sheets and placed in sealed envelopes, and then it will be given to the main researcher for studing. In this way, the patient and the evaluating physician, and the researcher will not be awared of any type of treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

participants; Research fellow; Clinical Attentive; The patient and the treating physician, who is responsible for evaluating the patient in terms of response to treatment,

and the researcher will not know the type of treatment assigned to the patient (drug or placebo). Equalization of medicated ointment and placebo is required for blinding, the base of medicated ointment and placebo is the same but herbal extract is not used in placebo, so to match medicated ointment and placebo for ointment color, USP Pharmacopoeia colors, and for specific ointment smell, USP Authorized essential oils will be used. ointments are finally coded by the coding system.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran University of Medical Sciences

Street address

Beginning of Valie Asr HighWay, Forked Road Of Jooybar, Emam Square, Sari

City

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Province

Mazandaran

Postal code

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Approval date

2021-10-09, 1400/07/17

Ethics committee reference number

IR.MAZUMS.REC.1400.483

Health conditions studied**1****Description of health condition studied**

Early chronic osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes**1****Description**

Dēcrease in Joint pain

Timepoint

0_14-28

Method of measurement

WOMAC standard questionnaire

Secondary outcomes

1

Description

Rigidity of Joints

Timepoint

0_14_28

Method of measurement

WOMAC

2

Description

Physical Disability

Timepoint

0-14-28

Method of measurement

WOMAC

Intervention groups

1

Description

Intervention group: time of intervention is 4 weeks and pain control test is WOMAC index and it is used in time 0 ,2 ,4 week after initiating of therapy. medicine will be used TID ,and a fingertip unit. E.M extract +Eucerin+Antioxidant is used ,in topical ointment. Consume Selexib 100mg BD and omega 3 at a rate of 1 per day.

Category

Treatment - Drugs

2

Description

Control group: If both knees of the patient are involved, the criterion for evaluation is the knee that has more pain and limitation of movement. However, in order to simulate the color of the ointment, the authorized food colors of Pharmacopeia USP will be used. The number of uses is three times a day and each time it is the amount of a finger. The duration of use is up to 4 weeks continuously. Consume Selexib 100mg BD and omega 3 at a rate of 1 per day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bagban Romatology Clinic(TOoba)Mazandaran university of Medical Science

Full name of responsible person

DR.Mohammad Yousef poor

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Beginning of Valiasr Highway, forked Road of

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr.Majid Saeedi

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr.Mohammad Yoosef Poor

Position

Iranian Medical Manager

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Danesh Pazhuhan Adonis Group(DPAG)

Full name of responsible person

Dr.Faranak Zaker

Position

Manager and Consultant

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data**Contact****Name of organization / entity**

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Other areas of specialty/work

Medical Pharmacy

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Province

Tehran

Postal code

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Phone

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Email

fara_zk@yahoo.com

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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Title and more details about the data/document

Data on primary outcomes and, if created, data on
secondary outcomes

When the data will become available and for how long

6 months after printing of results

To whom data/document is available

Researchers Producers

Under which criteria data/document could be used

use of documents in the way of research is acceptable.
commitment on not to use of documents in the way the
same research and production that we do.

From where data/document is obtainable

Dr.Mohammad Yousofpoor(MAZUMS)
m.yousofpoor@yahoo.com 00981133243117 Dr.Faranak
Zaker_Danesh Pazhuhan Adonis Group(DPAG)
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What processes are involved for a request to access data/document

connection with DANESH PAZHOOHAN ADONIS.Dr
Faranak Zaker Connection with Mazandaran University of
Medical Science.Dr Mohhamad Yousofpoor approximately
one month after publication

Comments