

# 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](http://www.randomization.com) and [www.randomizer.org](http://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)

##### Phone

+98 21 8820 0110

##### Email address

fara\_zk@yahoo.com

##### 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**

Sari

**Province**

Mazandaran

**Postal code**

4815733971

**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

##### Street address

Beginning of Valiasr Highway, forked Road of

Jooybar, Emam Square

##### City

sari

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##### Phone

+98 11 3304 4000

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##### Email

fara\_z@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Dr.Majid Saeedi

##### Street address

Beginning of Valiasr Highway\_Jooybar Forked road\_Emam Square

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##### Province

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##### Postal code

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##### Phone

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##### Email

majsaeedi@gmail.com

#### 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

**Street address**

Faculty of Iranian Medical ,Bagban specific  
Clinic,khazar BLV

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Sari

**Province**

Mazandaran

**Postal code**

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**Phone**

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**Email**

m.yousofpoor@yahoo.com

**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

**Street address**

18\_yas complex\_Bahar Alley\_North Shahin\_Jannat  
abad

**City**

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**Province**

Tehran

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**Email**

fara\_zk@yahoo.com

**Person responsible for updating data****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

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**Email**

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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**

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)  
fara\_zk@yahoo.com 00982144434912

**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**