

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Pilot evaluation of Marhame-Mafasel ointment in patients with knee osteoarthritis: a double-blind randomized trial

Protocol summary

Study aim

Evaluation of Marhame-Mafasel ointment and Diclofenac gel effect in patients with moderate knee osteoarthritis and evaluation of inflammatory factors and cytokines

Design

Randomized Double-Blind, Controlled Clinical Trial, parallel, Phase 2-3 on 66 patients with moderate knee osteoarthritis (33 patients in each group) using computer randomization method.

Settings and conduct

This study was conducted on 66 outpatients referring to Rheumatology Clinic, Imam Khomeini Hospital Complex. Patients are classified into intervention groups after being informed about the study and obtaining informed consent. Ointments have no name and only numbers and are given to the patient. Tests and examinations are performed and compared before and after the intervention. Researchers, rheumatologists, and patients are unaware of the allocation of study groups.

Participants/Inclusion and exclusion criteria

inclusion criteria: Patient satisfaction and signing of the informed consent form, Patients with moderate knee osteoarthritis (according to Kellgren-Lawrence classification), individuals between 40-80 years
Exclusion criteria: Lack of cooperation of patients, Patients with mild or severe knee osteoarthritis, Allergy to topical Nonsteroidal anti-inflammatory drugs (NSAIDs), History of steroid injection into the knee joint in the past three months, Consumption of oral NSAID drugs, Asthma, or any liver or kidney disorders

Intervention groups

Intervention group: Marhame-Mafasel ointment, Use three times daily in the amount of 3 cm for 1 month for each knee
Control group: Diclofenac gel, Use three times daily in the amount of 3 cm for 1 month for each knee

Main outcome variables

Level measurement of inflammatory factors ESR, CRP, RF, CBC, Evaluation of inflammatory cytokines TNF- α , IL-6 in serum, calculation VAS Score, Evaluation of

WOMAC and WHOQOL quality of life questionnaire before and after treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201126049498N2**

Registration date: **2021-03-17, 1399/12/27**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-17, 1399/12/27**

Update count: **0**

Registration date

2021-03-17, 1399/12/27

Registrant information

Name

Abdolrahman Rostamian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6691 1294

Email address

ar.rostamian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-06, 1399/12/16

Expected recruitment end date

2021-08-07, 1400/05/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pilot evaluation of Marhame-Mafasel ointment in patients with knee osteoarthritis: a double-blind randomized trial

Public title

The evaluation of Marhame-Mafasel ointment in the treatment of patients with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient satisfaction and signing of informed consent form
Patients with moderate knee osteoarthritis (individuals who classified in grade 3 or moderate included moderate joint space narrowing according to Kellgren-Lawrence classification) individuals between 40-80 years

Exclusion criteria:

Lack of cooperation of patients
Patients with mild or severe knee osteoarthritis
History of allergy to topical Nonsteroidal anti-inflammatory drugs (NSAIDs)
Patients with a history of steroid injection into the knee joint in the past three months
Consumption of oral Nonsteroidal anti-inflammatory drugs (NSAIDs)
History of asthma or any liver or kidney disorders

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

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

Sample size

Target sample size: **66**

More than 1 sample in each individual

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

Sampling before and after treatment

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we used Random Allocation software for randomization. The random sequence of samples was performed equally as Intervention and Control groups using this software. For allocation concealment, sealed envelopes were used. In this method, each of the random sequences written on a card and is placed in the envelopes, respectively. Finally, the lid of the envelopes is glued and placed in a box, respectively. At the registration time, based on the order in which eligible participants enter the study, one of the envelopes of their choice will be opened and their assigned group will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Marhame-Mafasel ointment is a reddish-brown color with a predominant Turpentine odor. Diclofenac gel was simulated using food color and Turpentine oil In order to simulate Marhame-Mafasel ointment. The ointments were packaged in the same shape and coded by an expert one in the research center using Random Allocation Software. Researchers, patients, data collectors, and evaluators assess the outcome, are not aware of the contents of the package and grouping, and samples were delivered to patients randomly using Allocation concealment.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Shahed University Committee for Ethics in biomedical Research

Street address

Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2018-12-24, 1397/10/03

Ethics committee reference number

IR.SHAHED.REC.1397.087

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

Knee osteoarthritis

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Evaluation of ESR (Erythrocyte Sedimentation Rate)

Timepoint

1months after and before treatment

Method of measurement

2**Description**

Evaluation of CRP (C-Reactive Protein)

Timepoint

1 months after and before treatment

Method of measurement

Quantitative method with diagnostic kit

3**Description**

Evaluation of Rheumatoid Factor (RF)

Timepoint

1 months after and before treatment

Method of measurement

Quantitative method with diagnostic kit

4**Description**Assay of TNF- α (Tumor necrosis factor α)**Timepoint**

1 months after and before treatment

Method of measurement

ELISA method

5**Description**

Assay of Interleukin 6 (IL-6)

Timepoint

1 months after and before treatment

Method of measurement

ELISA method

6**Description**

Evaluation of WOMAC questionnaire or Western Ontario and McMaster Universities Osteoarthritis Index to measure and determine the severity of the disability

Timepoint

1 months after and before treatment

Method of measurement

Questionnaire

7**Description**

Evaluation of visual analog scale (VAS)

Timepoint

1 months after and before treatment

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

Evaluation of World Health Organization Quality of Life-BREF (WHOQOL-BREF)

Timepoint

1 months after and before treatment

Method of measurement

Questionnaire

Intervention groups**1****Description**

Intervention group: Marhame-Mafasel ointment contains Arnebia euchroma as the main plant, peppermint, and chamomile essential oil. Arnebia euchroma is a perennial herbaceous plant in the family Boraginaceae that has anti-inflammatory effects due to its alkannin and shikonin compounds. In this study, the amount of 3 centimeters of Marhame-Mafasel ointment for each knee, three times daily for 4 weeks was prescribed for the patient.

Category

Treatment - Drugs

2**Description**

Control group: Diclofenac is classified in a group of medications called nonsteroidal anti-inflammatory drugs (NSAIDs). Topical diclofenac relieves osteoarthritis pain and stiffness and improves physical function. In this study, the amount of 3 centimeters of Diclofenac gel for each knee, three times daily for 4 weeks was prescribed for the patient.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rheumatology Clinic, Imam Khomeini hospital, Tehran

Full name of responsible person

Abdolrahman Rostamian

Street address

Imam Khomeini Hospital Complex, Qarib Avenue, the end of Keshavarz Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Mohsen Naseri

Street address

Floor 2, No. 1471, North Kargar Ave, Enghelab Sq,
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naseri@shahed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahed University

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

Shahed University

Full name of responsible person

Azadeh Mizani

Position

Researcher

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

Tehran University of Medical Sciences

Full name of responsible person

Abdolrahman Rostamian

Position

Associate Professor of Rheumatology

Latest degree

Subspecialist

Other areas of specialty/work

Rheumatology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Email

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All impersonal data of the participants without any name; Information on the main implications and all the information obtained from the research were published in article.

When the data will become available and for how long

In the relevant article after its publication

To whom data/document is available

Everyone who has access to the published article

Under which criteria data/document could be used

After publication in the journal

From where data/document is obtainable

Article and Dr Azadeh Mizani as the main researcher
azadeh.mizani@yahoo.com

What processes are involved for a request to access data/document

An email to that person

Comments