Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 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

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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 oinment 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

Manual

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 euchoma 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
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Sponsors / Funding sources

1

Sponsor
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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
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
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Full name of responsible person
Azadeh Mizani
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Other areas of specialty/work
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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
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