

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of the Effect of "Herbal ointment (Ginger, Black Pepper and Rose)" with "Methyl Salicylate ointment" on Improving pain and functional disorders in patients with knee arthritis

Protocol summary

Study aim

Effect of herbal ointment on pain relief and osteoarthritis

Design

80 patients with severe and moderate knee pain will be divided randomly (with a randomized table), into two groups of 40, one group: ointment and the other group will receive methyl salicylate in three times a day for four weeks. Phase III clinical trial.

Settings and conduct

Patients are referred to researcher by two orthopedic or rheumatologic specialists from two treatment centers affiliated to Imam Reza and Ghaem Hospital in Mashhad. Researcher and responsible for collecting and analyzing data and writing articles are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: primary osteoarthritis in knee Pain: Score over 40 (Visual Scale) age:60 - 80 years exclusion criteria: Patient dissatisfaction Need for supplementary treatment Skin disease or ulceration at the place of Drug use Patients treated with hormonal drugs

Intervention groups

Intervention group: Herbal ointment: ginger, pepper and peppermint in knee osteoarthritis Control group: Methyl salicylate ointment in knee osteoarthritis

Main outcome variables

Reduce knee pain Increase knee performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171112037401N3**

Registration date: **2018-02-01, 1396/11/12**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-18, 1397/11/29**

Update count: **1**

Registration date

2018-02-01, 1396/11/12

Registrant information

Name

Mohammad Sabbaghi

Name of organization / entity

Mashhad medical univercity

Country

Iran (Islamic Republic of)

Phone

+98 51 3879 5189

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Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology, Mashhad University of Medical Sciences

Expected recruitment start date

2017-12-21, 1396/09/30

Expected recruitment end date

2018-07-21, 1397/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of "Herbal ointment (Ginger, Black Pepper and Rose)" with "Methyl Salicylate ointment" on Improving pain and functional disorders in patients with knee arthritis

Public title

Comparison of the Effect of "Herbal Ointment " with" Methyl Salicylate Ointment " in patients with knee arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Symptomatic primary osteoarthritis in knee approved by clinical or radiological criteria Pain: Score over 40 (Visual Scale) Age: 60 - 80 years

Exclusion criteria:

Patient dissatisfaction Drug use Patients treated with hormonal drugs

Age

From **60 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

Blinding (investigator's opinion)

Triple blinded

Blinding description

The participant - investigator - the outcome evaluation - the outcome of the safety committee and the data monitoring committee do not know what kind of ointment.

Placebo

Not used

Assignment

Parallel

Other design features

Herbal medicine design with Iranian medicine approach

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

University Avenue, Building Qureshi, research and technology Mashhad University of Medical Sciences

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Mashhad

Province

Razavi Khorasan

Postal code

vcresearch[at]mums.a

Approval date

2017-07-15, 1396/04/24

Ethics committee reference number

IR.MUMS.REC.1396.141

Health conditions studied

1

Description of health condition studied

Knee Osteoarthritis

ICD-10 code

m17.9

ICD-10 code description

Gonarthrosis

Primary outcomes

1

Description

Joint stiffness

Timepoint

Two weeks after start the treatment, then every two weeks for two months

Method of measurement

WOMAC questionnaire

2

Description

pain

Timepoint

Two weeks after start the treatment, then every two weeks for two months

Method of measurement

The VAS criterion

3

Description

Physical action

Timepoint

Two weeks after start the treatment, then every two weeks for two months

Method of measurement

WOMAC questionnaire

Secondary outcomes

1

Description

Dissatisfaction

Timepoint

Two weeks after start the treatment, then every two weeks for two months

Method of measurement
Discontinue the treatment

Intervention groups

1

Description

Intervention group 1: prescribing herbal ointment containing the juice of three plants: pepper, cinnamon, and roses with equal ratio in a base of animal oil lubricant base, will give to three doses daily for two months. Ointment is made at the Mashhad Faculty of Traditional Medicine.

Category

Treatment - Drugs

2

Description

Intervention group 2: Methyl salicylate ointment 30 g (each 100 g contain 15 g of methyl salicylate and 10 g of menthol) made by Sobhan-Dar company is given in three daily doses for two months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

The Center for Health17shahrivar

Full name of responsible person

Dr.mohammad sabbaghi

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shirudi street 16-18

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences ,Vice chancellor for research

Full name of responsible person

Dr.tafaggodi

Street address

Ghoreishi Building, Danegah Street,Vice chancellor for research, University of Medical Sciences, Mashhad

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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

Mashhad University of Medical Sciences ,Vice chancellor for research

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

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Sabbaghi

Position

MD

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad Faculty of Traditional Medicine

Full name of responsible person

Mohammadreza Noras

Position

Phd student Traditional Medicine

Latest degree

Specialist

Other areas of specialty/work

Medical Education

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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