Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Email address
sabbaghim2@mums.ac.ir

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

City

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
Street address
shirudi street 16-18
City
Mashhad
Province
Razavi Khorasan
Postal code
9167763643
Phone
+98 51 3851 0874
Fax
+98 51 3879 5189
Email
sabbaghim2@mums.ac.ir
Web page address
http://mums.ac.ir

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, Danehgah Street,Vice chancellor for research, University of Medical Sciences, Mashhad
City
mashhad
Province
Razavi Khorasan
Postal code
RIS@mums.ac.ir
Phone
+98 51 3841 1538
Fax
+98 51 3841 1538
Email
RIS@mums.ac.ir
Web page address
http://mums.ac.ir
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
Street address
Shirudi street 16-18The Center for Health17shahrivar
City
Mashad
Province
Razavi Khorasan
Postal code
9167763643
Phone
+98 51 3364 7827
Fax

+98 51 3879 5189
Email
sabbaghim2@mums.ac.ir
Web page address
http://mums.ac.ir

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
Street address
Mashhad University of Medical Sciences -Mashhad Faculty of Traditional Medicine
City
Mashhad
Province
Razavi Khorasan
Postal code
norasmr@mums.ac.i
Phone
+98 51 3855 2189
Fax
+98 51 3853 5980
Email
norasmr@mums.ac.ir
Web page address
http://mums.ac.ir

Person responsible for updating data

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
Street address
Shirudi street 16-18The Center for Health17shahrivar
City
Mashhad
Province
Razavi Khorasan
Postal code
9718633854
Phone
+98 51 3364 7827
Fax
+98 51 3879 5189
Email
sabbaghim2@mums.ac.ir
Web page address
http://mums.ac.ir

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