Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A clinical trial comparing the effects of Galbanum oil and Diclofenac gel in patients pain with osteoarthritis of the knee

Protocol summary

Summary

Effects of Galbanum oil on patients pain with osteoarthritis of the knee, blocked randomized, single blind, control with standard medication, single center, phase 2 trial, inclusion criteria: eighteen to eighty years old; at least one knee pain lasting one month; radiographic changes including osteophyte and joint space narrowing(grade 1,2,3); pregnancy test in fertile women. Exclusion criteria: active infectious disease; skin lesion in knee; renal failure; knee surgery in 2 last months; alcohol or opioid abuse; pregnancy or breastfeeding; allergy to oil, sample size: 30 intervention: intervention group give Galbanum oil, oral acetaminophen and quadriceps femoris exercise and control group give topical Diclofenac gel, oral acetaminophen and quadriceps femoris exercise, intervention time: 4 weeks, primary outcome: knee pain severity, knee stiffness, pain interfering with daily activity and patients quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102719699N1**
Registration date: **2015-04-29, 1394/02/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-04-29, 1394/02/09

Registrant information

Name

Majid Khamessi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1679

Email address

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Recruitment status

Recruitment complete

Funding source

Myself

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial comparing the effects of Galbanum oil and Diclofenac gel in patients pain with osteoarthritis of the knee

Public title

Effect of Galbanum oil on pain of the knee arthrosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: eighteen to eighty years old; at least one knee pain lasting one month; radiographic changes including osteophyte and joint space narrowing (grade 1,2,3); pregnancy test in fertile women. Exclusion criteria: active infectious disease; skin lesion in knee; renal failure; knee surgery in 2 last months; alcohol or opioid abuse; pregnancy or breastfeeding; allergy to oil.

Age

From **18 years** old to **80 years** old

Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Patients and analyzers of the data are unaware of the drugs.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
School of medicine, Iran University of Medical Sciences, Hemmat highway between Chamran and Sheikh fazlollah
City
Tehran
Postal code
Approval date
2014-10-14, 1393/07/22
Ethics committee reference number
3296/ 105/ 93 /د

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis
ICD-10 code
M17.0
ICD-10 code description
Primary gonarthrosis, bilateral

Primary outcomes

1

Description
Knee pain severity
Timepoint
Before intervention, one month and two months after intervention
Method of measurement
Visual analog scale

2

Description
Knee pain, stiffness and interference with daily activity
Timepoint
Before intervention, one month and two months after intervention
Method of measurement
WOMAC questionnaire

Secondary outcomes

1

Description
Oral analgesic consumption
Timepoint
Before intervention, one month and two months after intervention
Method of measurement
Check list

2

Description
Skin hypersensitivity reactions
Timepoint
Before intervention, one month and two months after intervention
Method of measurement
Check list

Intervention groups

1

Description
Intervention 1, topical Galbanum oil/3 time a day, Acetaminophen 500 mg/ if needed, Quadriceps femoris exercise/ 3 time a day for 4 weeks. Sixty grams of Galbanum ointment given to each patient. Each gram contains 8.5 mg 1, 8 cineole and created by traditional medicine specialist.
Category
Treatment - Drugs

2

Description
Intervention 2, topical Diclofenac gel/ 3 time a day, Acetaminophen 500 mg/ if needed, Quadriceps femoris exercise/ 3 time a day for 4 weeks. Sixty grams of Diclofenac gel given to each patient. Each gram contains

1 mg Diclofenac sodium and created by Razak company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Majid Khamessi

Street address

Department of Physical Medicine and Rehabilitation, Firoozgar hospital, Behafarin street, Valiasr square, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Seyed Ali Javad Mousavi

Street address

Vice chancellor for research, Iran University of Medical Sciences, Hemmat highway between Chamran and Sheikh fazlollah, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Bijan Forough

Position

Physical Medicine and Rehabilitation specialist

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Majid Khamessi

Position

Physical Medicine and Rehabilitation resident/MD

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty