

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

khamesi.majid@yahoo.com

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 /ۛ

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

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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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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