

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Assessment of Topical Oil Melilotus officinalis effect on clinical sings of primary knee Osteoarthritis versus Diclofenac gel : A double blind study

Protocol summary

Summary

Main goal Comparing the effect of Melilotus officinalis oil and Diclofenac gel on early osteoarthritis of elders
Design and Method: People over 60 years old Residents of nursing homes of Tehran that complain from knee pain and their knee osteoarthritis confirmed by physical medicine specialist or orthopedic and after viewing radiographic. Study is a randomized, double-blind clinical trial. At the beginning of the study and Getting permission , information about the disease, and drugs, recorded according to their medical records. after explaining details of intervention patients entered to the study and if wish to participate in the study informed consent letter be completed by them. Basic information, including womac questionnaire, visual analogue scale, and demographic questionnaire asked them and randomly based on randomize tables divided to the control or intervention groups Intervention Way of used drougs , is about palm or 5 drops of oil Melilotus officinalis (intervention) and also one palm Diclofenac gel in front knee twice in day (control) Inclusion and exclusion criteria are as follows: Inclusion criteria 1. 60 years old and older 2. Weak to moderate Osteoarthritis (grade 1 to 3 based on criteriaa 3. The existence of moderate pain, according to VAS 4week befor intervention Exclusion criteria: 1. Sensitivity, and allergies, to Melilotus officinalis vegetable oil and Diclofenac gel 2. skin lesion in the knee area. 3. secondary osteoarthritis in the rheumatic diseases such as rheumatoid arthritis, gout, septic arthritis, metabolic arthritis, traumatic arthritis 4. Patients who had joint replacement with surgery

General information

Acronym

primary knee Osteoarthritis

IRCT registration information

IRCT registration number: **IRCT2016082129461N1**

Registration date: **2017-01-09, 1395/10/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-01-09, 1395/10/20

Registrant information

Name

Gholam Reza Ansari

Name of organization / entity

University of Rehabilitation Sciences and Social Welfare

Country

Iran (Islamic Republic of)

Phone

+98 21 8865 0958

Email address

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Recruitment status

Recruitment complete

Funding source

University of Welfare and Rehabilitation Research Center

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of Topical Oil Melilotus officinalis effect on clinical sings of primary knee Osteoarthritis versus Diclofenac gel : A double blind study

Public title

Effect of Topical Oil Melilotus officinalis on primary knee Osteoarthritis versus Diclofenac gel

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 60 years old and older ;pain at least in one knee over the last 3 months; Weak to moderate osteoarthritis (grade 1 to 3 based on criteria) Kellegren-Lawrence (K-L) grading scale; The existence of moderate pain, with minimum galling, according to VAS, at least for four weeks before entering the random assignment

Exclusion criteria: Sensitivity, and allergies, to Melilotus officinalis vegetable oil and Diclofenac gel; Skin lesion in the knee area; Secondary osteoarthritis in the rheumatic diseases such as rheumatoid arthritis, gout, septic arthritis, metabolic arthritis, traumatic arthritis; Patients who had joint replacement with surgery ; Using from oral and local, steroids, within 14 days before study; Injecting the, intra-articular steroid within 90 days before study; Alcoholism, and addiction to drugs; Having radiculopathy and neuropathy

Age

From **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

University of Rehabilitation Sciences and Social Welfare

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Koodakyar street. Boulevard student . Evin. Tehran
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Postal code

Iran

Approval date

2016-05-23, 1395/03/03

Ethics committee reference number

IR.USWR.REC.1395.51

Health conditions studied**1****Description of health condition studied**

Primary osteoarthritis

ICD-10 code

M15.0

ICD-10 code description

Primary generalized (osteo)arthrosis M15.0

Primary outcomes**1****Description**

Improve of Physical Activity

Timepoint

in beginning of intervention; 2 and 4 week after beginningintervention

Method of measurement

questionnaire

Secondary outcomes**1****Description**

Decrease of pain

Timepoint

beginning of intervention; 2 and 4 week after beginningin
tervention

Method of measurement

questionnaire

Intervention groups**1****Description**

5 drops Oil Melilotus officinalis in the front knee In the morning and evening

Category

Treatment - Drugs

2**Description**

5Drop of Diclofenac gel in front of knee In the morning and evening

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kahrizak Charity Foundation in Tehran

Full name of responsible person

Gholam Reza Ansari

Street address

Kahrizak, the end of the boulevard Doctor Hakim zadeh. Qom old road after Bhsht zahra, Tehran, Iran

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Welfare and Rehabilitation Research
Center

Full name of responsible person

Robab Sahaf

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Welfare and Rehabilitation Sciences University /
Center for Aging Research. Tehran

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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

University of Welfare and Rehabilitation Research Center

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

Kodakyar deadlock Boulevard student Evin field .
Welfare and Rehabilitation Sciences University / Ce

Full name of responsible person

Gholam Reza Ansari

Position

MPH Student

Other areas of specialty/work**Street address**

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

PHD Gerontology

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Web page address**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