Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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
Street address
Koodakyar street. Boulevard student . Evin. Tehran Tehran Tehran Iran, Islamic Republic Of 00982122180154 00989128204187
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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 osteoarthrit
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

City
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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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Kodakyar deadlock Boulevard student Evin field . Welfare and Rehabilitation Sciences University / Center for Aging Research. Tehran

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Tehran

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

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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