Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of Shebet Oil and Diclofenac Gel on clinical symptoms in patients with Knee osteoarthritis: A randomized, double-blind, controlled Clinical trial

Protocol summary

Summary

This is a Double-Blinded Randomized clinical study to compare the effects of herbal Shebet Oil with diclofenac gel on patients with clinical symptoms of knee osteoarthritis. 80 patients according to ACR classification criteria by the rheumatologist, Patient's written consent, Osteophyte in radiography, Knee pain associated with one of these symptoms: (age older than 50 years, following 30 minutes of morning stiffness, Knee Crepitus) in the age range 80-40 years are accepted. They will allocate to two arms using block randomization. Drugs will be encoding, same shape and without the name, 2 grams, three times a day for 4 weeks will prescribe to intervention groups(Both groups). Body weight, Height, CBC, Diff, BUN, Cr, ALT, AST will measure at the beginning time and after 4 weeks just repeated mentioned experiments. Patients two weeks after the start and after 4 weeks of treatment (end of study) are examined by the rheumatologist and the relevant data through interviews and examination of them will be collected.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012055315N1**
Registration date: **2011-04-20, 1390/01/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-04-20, 1390/01/31

Registrant information

Name

Mahmood Khodadoost

Name of organization / entity

Iranian Traditional Medicine College

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Shahed college of Medcine

Expected recruitment start date

2010-07-14, 1389/04/23

Expected recruitment end date

2011-07-14, 1390/04/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Shebet Oil and Diclofenac Gel on clinical symptoms in patients with Knee osteoarthritis: A randomized, double-blind, controlled Clinical trial

Public title

Effect of Shebet Oil on Knee Arthrosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion critria: Patient's written consent for inclusion, Osteophyte in X.Ray, Knee pain Plus at least one of three: (Age>50 year, Stiffness<30 minutes, Crepitus). Exclusion Critria: Those who need more than 2 grams of

acetaminophen ,Those who need to use other oral or intravenous analgesic ,Unwillingness to continue to participate in the study, Sensitivity to study drugs, Patients with other bone joint disorders:(Rhumatoid Arthrities, Gout,Pseudo Gout, Infected Arthrities, Metabolic Arthrities, Traumatic Arthrities), Joint Replacement, fibro Myalgia, Non-motor dysfunction related to hip or knee(Radiculopathy and Neuropathy), Concomitant use of glucosamine and chondrotin sulfate Knee Articular, Knee corticosteroid injection in the past 3 months, Other Articular corticosteroid injection in the past 1 months, Taking muscle relaxant drugs, Pregnancy, Oral and Local use of Corticosteroid in 14 past days, Mussle corticosteroid injection in the past 1 months Alcohol addicted, Drug Abuse, Skin Diseases in Knee, Pationts with active Renal, Liver and Peptic Ulcer Diseases, Low dose Antidepressant user for chronic pain.

Age
From **40 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Traditional Medcine College, Tehran University of Medical science

Street address
Traditional Medcine College, Tehran University of Medical science, Farre danesh Alley, Ghods Avenue

City
Tehran

Postal code
1417744391

Approval date
2011-02-15, 1389/11/26

Ethics committee reference number
200/7029

Health conditions studied

1

Description of health condition studied
Arthritis

ICD-10 code
M19

ICD-10 code description
Primary arthrosis of other joints

Primary outcomes

1

Description
Overall patient satisfaction

Timepoint
2 Weeks

Method of measurement
Ask the patient

2

Description
Physical performance

Timepoint
2 Weeks

Method of measurement
Womac Test

3

Description
Stifness

Timepoint
2WEEKS

Method of measurement
womac Test

4

Description
Pain

Timepoint
2 Weeks

Method of measurement
Womac Test

Secondary outcomes

empty

Intervention groups

1

Description
shebet oil. Knee local use. Dosage 2 grams per use 3 times a day. Patients will be visited at the 0, 2, 4 weeks of the study.

Category

Treatment - Drugs

2

Description
Pluse control group: diclofenac gel group. Knee local use. Dosage 2 grams per use 3 times a day. Patients will be visited at the 0, 2, 4 weeks of the study.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mostafa Khomeiny Hospital
Full name of responsible person
Dr.Mahmood Khodadoost
Street address
Italy Avenue, Mostafa Khomeiny Hospital
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Shahed college of Medcine
Full name of responsible person
Dr.Davati
Street address
Medical college, Abdollah zadah street, keshavarz B.L.V.
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,Shahed college of Medcine
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