Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Clinical trial comparing the effects of Pistacia atlantica oleoresin and placebo on the joint pain and stiffness and physical function in the knee osteoarthritis patients

Protocol summary

Summary

Objective: comparing the efficacy of Pistacia atlantica oleoresin and placebo in the treatment of knee osteoarthritis patients. Study design: randomized, double-blind, placebo-controlled, two group parallel design, single-center, phase 2 of clinical trial. Study population: patients with knee osteoarthritis. Sample size: 100 patients. Inclusion criteria: male or female patients with 1 or 2 knees osteoarthritis according to the American College of Rheumatology criteria after physical examination and knee joint radiography, age of 40 to 85 years, flare of the disease after oral non-steroidal anti-inflammatory drug or acetaminophen discontinuation which have been used at least 3 days a week during the past month (flare means increase of at least 2 scores in the total pain subscale score in the beginning of the study), Western Ontario and McMaster Universities (WOMAC) pain subscale index at least 9 out of 20 in the beginning of the study. Exclusion criteria: secondary osteoarthritis (due to a definite disease); arthroscopy; surgery; knee joint injection during the past 6 months; history of knee replacement surgery; any serious systemic disease (such as concomitant infections, cardiovascular, hepatic and renal diseases); any other chronic inflammatory disease; intake of any other supplement except multivitamin; intake of non-steroidal anti-inflammatory drugs; intake of any steroidal drug, skeletal muscle relaxing drug, anti-depressant drugs, glucosamine, chondroitin, tramadol and topical analgesic drugs like capsaicin and generally any analgesic drug; any history of alcohol, drug and narcotics abuse; skin disease at the site of topical use of the oleoresin or placebo (knee); having fibromyalgia and other debilitating diseases affecting the knee; pregnant women; women planning pregnancy; lactating women. Interventions: Pistacia atlantica oleoresin skin ointment is administered to a group of about 50 patients every 8 hours on the knee for 1 month and placebo skin ointment is administered to another parallel group of about 50 patients every 8 hours on the knee for 1 month. Before intervention and 1 month after intervention, the primary and secondary outcome variables are evaluated. Primary outcome variables: extent of arthritis, extent of joint pain, extent of joint stiffness, extent of physical function. Secondary outcome variable: dose of acetaminophen.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610162288N10**
Registration date: **2016-12-21, 1395/10/01**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-12-21, 1395/10/01

Registrant information

Name

Saeed Kianbakht

Name of organization / entity

Iranian Academic Center for Education, Culture and Research Institute of Medicinal Plants

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Recruitment status

Recruitment complete

Funding source

The Vice Chancellor for research of the ACECR Institute

of Medicinal Plants and the Tehran University of Medical Sciences.

Expected recruitment start date
2017-04-21, 1396/02/01
Expected recruitment end date
2019-04-21, 1398/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial comparing the effects of Pistacia atlantica oleoresin and placebo on the joint pain and stiffness and physical function in the knee osteoarthritis patients

Public title
Effect of Pistacia atlantica resin in the treatment of knee arthrosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: male or female patients with 1 or 2 knees osteoarthritis according to the American College of Rheumatology criteria after physical examination and knee joint radiography, age of 40 to 85 years, flare of the disease after oral non-steroidal anti-inflammatory drug or acetaminophen discontinuation which have been used at least 3 days a week during the past month (flare means increase of at least 2 scores in the total pain subscale score in the beginning of the study.), Western Ontario and McMaster Universities (WOMAC) pain subscale index at least 9 out of 20 in the beginning of the study.
Exclusion criteria: secondary osteoarthritis (due to a definite disease); arthroscopy; surgery; knee joint injection during the past 6 months; history of knee replacement surgery; any serious systemic disease (such as concomitant infections, cardiovascular, hepatic and renal diseases); any other chronic inflammatory disease; intake of any other supplement except multivitamin; intake of non-steroidal anti-inflammatory drugs; intake of any steroidal drug, skeletal muscle relaxing drug, anti-depressant drugs, glucosamine, chondroitin, tramadol and topical analgesic drugs like capsaicin and generally any analgesic drug; any history of alcohol, drug and narcotics abuse; skin disease at the site of topical use of the oleoresin or placebo (knee); having fibromyalgia and other debilitating diseases affecting the knee; pregnant women; women planning pregnancy; lactating women.
Age
From **40 years** old to **85 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Block randomization with computer generated random numbers table and sequentially numbered containers each representing a block consisting of two patients are used for the treatment assignments.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Enghelab Avenue
City
Tehran
Postal code
Approval date
2016-10-15, 1395/07/24
Ethics committee reference number
1395.2852.IR.TUMS. REC

Health conditions studied

1

Description of health condition studied
Osteoarthritis
ICD-10 code
M19.9
ICD-10 code description
Arthrosis, unspecified

Primary outcomes

1

Description
Extent of arthritis
Timepoint
Before intervention and 1 month after intervention
Method of measurement
The Western Ontario and McMaster Universities Arthritis Index questionnaire

2

Description
Extent of joint pain
Timepoint
Before intervention and 1 month after intervention
Method of measurement
The Western Ontario and McMaster Universities Arthritis Index questionnaire

3

Description
Extent of joint stiffness
Timepoint
Before intervention and 1 month after intervention
Method of measurement
The Western Ontario and McMaster Universities Arthritis Index questionnaire

4

Description
Extent of physical function
Timepoint
Before intervention and 1 month after intervention
Method of measurement
The Western Ontario and McMaster Universities Arthritis Index questionnaire

Secondary outcomes

1

Description
Dose of acetaminophen
Timepoint
Before intervention and 1 month after intervention
Method of measurement
Daily recording of the acetaminophen dose by the patient

Intervention groups

1

Description
Pistacia atlantica oleoresin skin ointment is administered to a group of about 50 patients every 8 hours on the knee for 1 month.
Category
Treatment - Drugs

2

Description
Placebo skin ointment is administered to another group of about 50 patients every 8 hours on the knee for 1 month.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Shariati Hospital
Full name of responsible person
Dr. Ahmad Reza Jamshidi
Street address
Kargar Shomali Avenue
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, ACECR Institute of Medicinal Plants
Full name of responsible person
Dr. Reza Hajiaghaee
Street address
ACECR Complex, Supa Boulevard, Poleh Kordan
City
Karaj
Grant name
2012
Grant code / Reference number
2012
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, ACECR Institute of Medicinal Plants
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Vice Chancellor for Research, Tehran University of Medical Sciences
Full name of responsible person
Dr. Mehdi Mahmoodi
Street address
Rheumatology Research Center, Dr. Shariati Hospital, Kargar Shomali Avenue
City
Tehran

Grant name
01-95
Grant code / Reference number
95-01
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Tehran University of Medical Sciences
Proportion provided by this source
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
ACECR Institute of Medicinal Plants
Full name of responsible person
Dr. Saeed Kianbakht
Position
Ph.D. in pharmacology, assistant professor of the department of pharmacology and applied medicine in
Other areas of specialty/work
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Person responsible for scientific inquiries

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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