

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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Iran (Islamic Republic of)

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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

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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*