Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of pistacia atlantica oleoresin (saqez) and diclofenac gel on clinical symptoms in patients with knee osteoarthritis : A double-blind , controlled trial.

Protocol summary

Summary

This is a double-blinded randomized clinical study to compare the effects of herbal pistacia atlantica oleoresin (saqez) cream with diclofenac gel on patients with clinical symptoms of knee osteoarthritis. 84 patients with ACR criteria (grade 2 and 3) with radiographic evidence between the ages of (35-85) and final diagnosis by the rheumatologist will be entered. They will be allocated in to two arms in random. The drugs will be encoded, same shape without the name, 2 grams, 3 times a day for 12 weeks prescribed to both groups. Those patients who are unwilling to continue to participate in the study or sensitivity to the offered study drugs will be excluded. Patients at the base line, week 2, week six and week twelve will be reviewed on physical function, stiffness, pain and total symptoms with womac questionaries.

General information

Acronym

OA osteoarthritis

IRCT registration information

IRCT registration number: **IRCT201506073106N26**
Registration date: **2015-07-06, 1394/04/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-07-06, 1394/04/15

Registrant information

Name

Farshad Hashemian

Name of organization / entity

Pharmaceutical Sciences Branch, Islamic Azad University (IAU)

Country

Iran (Islamic Republic of)

Phone

+98 21 2260 0037

Email address

hashemian.f@iaups.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigators financial sources and Islamic azad university

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2015-07-06, 1394/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of pistacia atlantica oleoresin (saqez) and diclofenac gel on clinical symptoms in patients with knee osteoarthritis : A double-blind , controlled trial.

Public title

Effect of saqez cream on knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patient's written consent; radiographic changes; primary knee osteoarthritis grade 2 and 3; age between 35 – 85; patients who did not receive topical treatment or received previous topical treatment for at least two weeks before they start on this trial. All

patients must be stable on their current oral therapy. Exclusion criteria: Patients who needs more than 2 grams of acetaminophen in order to control pain; Those who need to use other oral or intravenous analgesics; Unwilling to continue or to participate in the study any further; Sensitivity to study drugs; Patients with other bone joint disorders: (Rhumatoid Arthrities, Gout, Pseudo Gout, Infected Arthrities, Metabolic Arthrities, Traumatic Arthrities) ; Infections and malignancy disease; Joint replacement; Fibro myalgia; Knee corticosteroid injection in the past 3 months, Pregnancy, oral and local use of corticosteroids; Patients with active Renal, Liver and Peptic Ulcer Disease; Alcohol addicted; Drug Abuse

Age
From **35 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **85**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of pharmaceutical science branch of Islamic Azad University

Street address
No.99, Yakhchal street, Dr. Shariati Avenue Tehran

City
Tahran

Postal code

Approval date
2012-06-20, 1391/03/31

Ethics committee reference number
3332

Health conditions studied

1

Description of health condition studied
Osteoarthritis

ICD-10 code
M19.0

ICD-10 code description
Primary arthrosis of other joints

Primary outcomes

1

Description
Physical function

Timepoint
2 Weeks,6 weeks and 12 weeks after baseline

Method of measurement
Womac questionaries

2

Description
Stiffness

Timepoint
2 Weeks,6 weeks and 12 weeks after baseline

Method of measurement
Womac questionaries

3

Description
Pain

Timepoint
2 Weeks,6 weeks and 12 weeks after baseline

Method of measurement
Womac questionaries

Secondary outcomes

empty

Intervention groups

1

Description
Saqez cream prepared by researcher, Knee local use, Dosage 2 grams per use, 3 times a day for 3 months

Category
Treatment - Drugs

2

Description
Pluse control group: diclofenac gel 1 % (Iran najo) ,3 times daily, 2 grams, for 3 months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Bu-Ali hospital

Full name of responsible person
Dr. Mehdi Rajabi

Street address
Bu-Ali hospital, Damavand avenue, Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University, Pharmaceutical Sciences Branch

Full name of responsible person
Dr. Sepideh Arbabi Bidgoli

Street address
No.99, Yakhchal street, Dr. Shariati Avenue Tehran

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Islamic Azad University, Pharmaceutical Sciences Branch

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
Islamic Azad University, Pharmaceutical Sciences Branch

Full name of responsible person
Dr. Mehdi Rajabi

Position
Assistant professor / Head of Clinical Pharmacy Department

Other areas of specialty/work

Street address
No.99, Yakhchal street, Dr. Shariati Avenue

City
Tehran

Postal code

Phone
+98 21 2264 0056

Fax

Email
mehdirj@aol.co.uk

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University, Pharmaceutical Sciences Branch

Full name of responsible person
Dr. Mehdi Rajabi

Position
Assistant professor / Head of Clinical Pharmacy Department

Other areas of specialty/work

Street address
No.99, Yakhchal street, Dr. Shariati Avenue

City
Tehran

Postal code

Phone
+98 21 2264 0056

Fax

Email
mehdirj@aol.co.uk

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University, Pharmaceutical Sciences Branch

Full name of responsible person
Mahtab Peivastegan

Position
Pharmacist

Other areas of specialty/work

Street address
NO 8 - sabouri alley - hengam avenue - resalat square

City
Tehran

Postal code
1677769513

Phone
+98 21 7744 0246

Fax

Email
drmp66@gmail.com

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