

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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: ( Rheumatoid 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; Pations 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*