

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The Effect of a formulation containing Boswellia Serrata extract on the Osteoarthritis patients' pain alleviation and quality of life improvement and comparison with Placebo and Piroxicam Gel

Protocol summary

Study aim

Evaluation of the effect of Boswellia Serrata extract on OA Patients' Quality of Life Improvement

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

A double blind study on the effects of Boswellia Serrata extract on Osteoarthritis patient's QOL that will take place in Golestan Hospital, Ahvaz, Khuzestan, Iran. Patients, and the researchers are blinded

Participants/Inclusion and exclusion criteria

Patient's presenting with knee pain with Osteoarthritis as a diagnosis; at least three months since diagnosis; Visual Analog Scale score must be more than 40 after stopping the treatment for 7 days; Lequesne functional Index more than 7 after stopping the treatment for 7 days; Patients must have the ability to stand and walk and to provide written and oral consent;

Intervention groups

An intervention group using an ointment containing Boswellia Serrata Extract for 4 weeks three times a day A control group using Piroxicam ointment for 4 weeks three times a day A control group using Placebo ointment for 4 weeks three times a day

Main outcome variables

Stiffness of the Joint; Joint function; Pain; Quality of life;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190107042264N1**

Registration date: **2019-03-05, 1397/12/14**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-05, 1397/12/14**

Update count: **0**

Registration date

2019-03-05, 1397/12/14

Registrant information

Name

Ehsan Hedayatinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3334 3368

Email address

hedayatee.e@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-05-21, 1398/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of a formulation containing Boswellia Serrata extract on the Osteoarthritis patients' pain alleviation and quality of life improvement and comparison with Placebo and Piroxicam Gel

Public title

The Effect of Boswellia Serrata Extract on Osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
 Patient's presenting with knee pain with Osteoarthritis as a diagnosis at least three months since diagnosis Visual Analog Scale score must be more than 40 after stopping the treatment for 7 days Lequesne functional Index more than 7 after stopping the treatment for 7 days Patients must have the ability to stand and walk and to provide written and oral consent

Exclusion criteria:
 Allergy of any kind to Boswellia and any of it's derivatives Malignancy Patient's unresponsive to conventional treatment Inflammatory Arthropathies Hyperuricemia Surgery planned New injury in sight of OA Intraarticular corticosteroid injection in the past 3 months Liver or Renal Failure History of gastric ulceration Uncontrolled Hypertension Congestive Heart Failure Pregnancy

Age
 From **18 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
 Target sample size: **60**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Using Research Randomizer(freely available at www.randomizer.org) sixty random numbers are generated. this unsorted series of numbers are then used to assign coded drugs to patients.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 Drugs and placebo produced in the faculty of pharmacy in addition to Piroxicam gel were given to an independent group for packing. all the material is then packed in completely similar tubes, containing a numbered code and instructions on how to use. these tubes are then given to the clinical team for assigning to the patients. The patient, the researcher and the clinical team are kept unaware of the contents of each tube.

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Faculty of Medicine, Ahvaz Jundishapur University of Medical Sciences, Esfand Street, Golestan, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

1579461357

Approval date

2019-01-19, 1397/10/29

Ethics committee reference number

IR.AJUMS.REC.1397.787

Health conditions studied

1

Description of health condition studied

Osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Stiffness of the Joint

Timepoint

The beginning of the study, 7, 14, 28 days after start of drug use

Method of measurement

The Western Ontario and McMaster Universities Osteoarthritis Index

2

Description

Joint function

Timepoint

The beginning of the study, 7, 14, 28 days after start of drug use

Method of measurement

The Western Ontario and McMaster Universities Osteoarthritis Index; Lequesne Functional Index

3

Description

Pain

Timepoint

The beginning of the study, 7, 14, 28 days after start of drug use

Method of measurement
The Western Ontario and McMaster Universities Osteoarthritis Index; Visual Analog Scale

4

Description
Improvement in Quality of Life

Timepoint
The end of the study

Method of measurement
Summation and Analysis of The Western Ontario and McMaster Universities Osteoarthritis Index and Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Herbal Cream containing Boswellia Serrata Extract, Produced in Ahvaz Jundishapur University of Medical Sciences; 3 times a day for 4 weeks

Category
Rehabilitation

2

Description
Control group: Placebo cream, Produced in Ahvaz Jundishapur University of Medical Sciences, 3 times a day for 4 weeks

Category
Placebo

3

Description
Control group: Piroxicam 0.5% Gel , Produced by Razak Laboratories Co., 3 times a day for 4 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Golestan Teaching Hospital

Full name of responsible person
Karim Mowla

Street address
Golestan Teaching Hospital - Farvardin St - Golestan

City
Ahvaz

Province

Khouzestan

Postal code
6135733118

Phone
+98 61 3374 3001

Email
mowla-k@ajums.ac.ir

Web page address
<http://hgolestan.ajums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Karim Mowla

Street address
Golestan Teaching Hospital - Farvardin St - Golestan

City
Ahvaz

Province
Khouzestan

Postal code
6135733118

Phone
+98 61 3374 3001

Email
mowla-k@ajums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Ahvaz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Karim Mowla

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Golestan Teaching Hospital - Farvardin St - Golestan

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Phone

+98 61 3374 3001

Email

mowla-k@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Karim Mowla

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Golestan Teaching Hospital - Farvardin St - Golestan

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Phone

+98 61 3374 3001

Email

mowla-k@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Ehsan Hedayatinejad

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Faculty of medicine - Ahwaz Jundishapur University of Medical Sciences - Golestan

City

Ahwaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3334 3368

Fax

Email

Hedayatee.e@ajums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only a part of data will be published

When the data will become available and for how long

The data will be accessible until 6 months after the publication of the results

To whom data/document is available

The data will be available to researchers and scientists working in registered academic and scientific institutions

Under which criteria data/document could be used

The obtained data will be available for further analysis

From where data/document is obtainable

All interested parties should contact the corresponding author by e-mail

What processes are involved for a request to access data/document

after contacting the corresponding author, the data will be sent to Golestan hospital security for publication clearance, after the clearance, the data will be sent to the applicant

Comments