Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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, Khouzestan, 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
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Iran (Islamic Republic of)
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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

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Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Karim Mowla

Street address

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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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Ehsan Hedayatinejad
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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