# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Evaluation of the effect of Elaeagnus angustifolia alone and in combination with Boswellia thurifera compared with ibuprofen in patients with knee osteoarthritis

## Protocol summary


**Summary**

Objectives: 1. Determination and comparison of pain severity in patients with knee osteoarthritis before and after the interventions 2. Determination and comparison of function in patients with knee osteoarthritis before and after the interventions Design: - study groups: patients with knee osteoarthritis referring to Rheumatology clinic of Al-Zahra hospital of Isfahan - Groups and sample size: three 25-patient groups - Blinding: double-blind - Randomization: simple - Setting and conduction: for the three groups, the capsules of Elaeagnus angustifolia extract, Elaeagnus angustifolia/Boswellia thurifera extracts, and ibuprofen will be administered, respectivley. The values of variables before and after the intervention will be compared between the groups. Participants: 1. age of 40 to 80 years 2. having osteoarthritis of at least one knee for at least 6 months 3. no liver or renal dysfunction 4. no injection of intra-articular glucocorticoids within the past 3 months Intervention: - group 1: the capsule of Elaeagnus angustifolia extract (200 mg) three times daily - group 2: the capsule of Elaeagnus angustifolia/Boswellia thurifera extracts (200/100 mg) three times daily - group 3: the capsule of ibuprofen (400 mg) three times daily - duration: 4 weeks Main outcome measures: - the pain score using visual analogue scale (VAS) - the score of Lequesne's pain and function index (LPFI) - the score of global patients assessment (PGA)


## General information

**Acronym**

-

**IRCT registration information**

IRCT registration number: **IRCT2015072123282N1**
Registration date: **2015-09-09, 1394/06/18**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

**Registration date**

2015-09-09, 1394/06/18

**Registrant information**


**Name**

Rasool Soltani

**Name of organization / entity**

Isfahan University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 31 3792 7067

**Email address**

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**Recruitment status**

**Recruitment complete**


**Funding source**

Kashan Barij Essence Pharmaceutical Company and Vice Chancellor for Research, Isfahan University of Medical Sciences


**Expected recruitment start date**

2015-08-23, 1394/06/01

**Expected recruitment end date**

2015-11-21, 1394/08/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of Elaeagnus angustifolia alone and in combination with Boswellia thurifera compared with ibuprofen in patients with knee osteoarthritis

**Public title**
Evaluation of the effect of Elaeagnus angustifolia alone and in combination with Boswellia thurifera compared with ibuprofen in patients with knee osteoarthritis
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
Inclusion criteria: age of 40 - 80 years; Osteoarthritis of at least one knee for at least 6 months based on the diagnostic criteria of American College of Rheumatology (ACR); Pain score > 40 mm based on the visual analogue scale (VAS); CRP serum level < 10 mg/dL; LPFI (Lequesne Pain and Function Index) score > 7; Grade 2 or 3 of Kellgren-Laurence scale in knee radiography within the past 6 months Exclusion criteria: Dysfunction of either liver, kidneys, or cardiovascular system or malignancy; Use of intra-articular glucocorticoids within the past 3 months; Use of intra-articular sodium hyaluronate within the past 6 months; Use of systemic glucocorticoids (either oral or parenteral) within the past 3 months; Having other osteoarticular disorders (e.g., rheumatoid arthritis and gout); Uncontrolled hypertension (> 140/90 mm Hg); Increased ESR; Having gastric or duodenal ulcers (based on the medical history); Sensitivity to the intervention drug; Being candidate for arthroplasty surgery; Not use of the intervention drug for more than one week; Knee arthroscopy within the past 3 months; Illiteracy
**Age**
From **40 years** old to **80 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **75**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**
Randomization will be performed using random number table.

## Secondary Ids

**1**

**Registry name**
-
**Secondary trial Id**
-
**Registration date**
empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics committee of Isfahan University of Medical Sciences
**Street address**
Hezar-Jerib Avenue, Vice-chancellery for research, Isfahan University of Medical Sciences, Isfahan
**City**
Isfahan
**Postal code**
**Approval date**
2014-10-26, 1393/08/04
**Ethics committee reference number**
393538

## Health conditions studied

**1**

**Description of health condition studied**
knee osteoarthritis
**ICD-10 code**
M17.1
**ICD-10 code description**
Other primary gonarthrosis

## Primary outcomes

**1**

**Description**
Lequesne's Pain and Function Index (LPFI)
**Timepoint**
before the intervention and 4 weeks after the intervention
**Method of measurement**
Questionnaire

**2**

**Description**
visual analogue scale (VAS)
**Timepoint**
before the intervention and 4 weeks after the intervention
**Method of measurement**
scoring on the scale

**3**

**Description**
patient global assessment (PGA)
**Timepoint**
before the intervention and 4 weeks after the intervention
**Method of measurement**

scoring on the scale

## Secondary outcomes

### 1

**Description**
adverse effects
**Timepoint**
during the intervention
**Method of measurement**
patient report

## Intervention groups

### 1

**Description**
Intervention group 1: Elaeagnus angustifolia extract, capsule 200 mg (Barij Essence, Kashan), three times daily for 4 weeks
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group 2: Elaeagnus angustifolia extract/Boswellia thurifera extract, capsule 200 mg/100 mg (Barij Essence, Kashan), three times daily for 4 weeks
**Category**
Treatment - Drugs

### 3

**Description**
Control group: Ibuprofen, capsule 400 mg (Barij Essence, Kashan), three times daily for 4 weeks
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Rheumatology clinic of Al-Zahra hospital
**Full name of responsible person**
Rasool Soltani
**Street address**
Soffeh Avenue, Al-Zahra Educational and Therapeutic Center
**City**
Isfahan

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Barij Essence Pharmaceutical Company
**Full name of responsible person**
Valiollah Hajhashemi
**Street address**
Mashhad Ardehal
**City**
Kashan
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Barij Essence Pharmaceutical Company
**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 of Isfahan University of Medical Sciences
**Full name of responsible person**
Mehdi Nematbakhsh
**Street address**
Hezar-Jerib Avenue, Isfahan University of Medical Sciences
**City**
Isfahan
**Grant name**
-
**Grant code / Reference number**
-
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice-Chancellor for research of Isfahan 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**
Isfahan University of Medical Sciences
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Ph.D/Scientific member of university
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*