

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Evaluation the effect of ointment of pistacia Atlantica oil on primery knee osteoarthritis

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of ointment of pistacia Atlantica in relieving pain in primary osteoarthritis of the knee in comparison with diclofenac gel

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized with permutation blocks, phase 3 on 92 patients.

##### Settings and conduct

The treatment group is given an ointment containing pistacia Atlantica oil to be applied three times a day at the rate of one finger on the knee joint and the surrounding areas for 4 weeks, and in the control group diclofenac is given in the same package. The use of the drug by each volunteer is monitored weekly by the student conducting the project. In the second stage, 4 weeks and 8 weeks after starting the drug, pain is re-evaluated through questionnaires.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 50 to 80 years. Severity of grade 1 to 3 osteophytes based on KL classification in graph VAS score between 3 and 8 exclusion criteria: Attend another clinical study in the last 6 months. Cognitive or mental disorders and chronic untreated diseases or drug allergies Taking oral and injectable corticosteroids in the last two months Joint replacement through surgery Patients taking concomitant glucosamine, chondroitin sulfate, and muscle relaxants

##### Intervention groups

In the treatment group, the ointment containing pistacia Atlantica oil is rubbed three times a day on the knee joint and the surrounding areas three times a day for 4 weeks, and in the control group, diclofenac is given in the same package.

##### Main outcome variables

Therapeutic groups, joint's Pain, joint's Symptoms, Activities of Daily Living, Sport, Quality of Life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210513051279N1**

Registration date: **2021-06-27, 1400/04/06**

Registration timing: **prospective**

Last update: **2021-06-27, 1400/04/06**

Update count: **0**

##### Registration date

2021-06-27, 1400/04/06

##### Registrant information

##### Name

fatemeh azizi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3219 4730

##### Email address

f.azizi@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-07-22, 1400/04/31

##### Expected recruitment end date

2022-09-21, 1401/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation the effect of ointment of pistacia Atlantica oil on primery knee osteoarthritis

#### Public title

Evaluation the effect of ointment of pistacia Atlantica oil on primery knee osteoarthritis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

age between 50 to 80 years osteoarthritis grade 1 to 3 according to Kellgren-Lawrence Classification of Osteoarthritis in X Ray severity of pain 3 to 8 in VAS scale

##### Exclusion criteria:

Attend another clinical study in the last 6 months  
Cognitive or mental disorder  
Taking oral and injectable corticosteroids in the last two months  
People who have a history of allergies to herbal medicines  
Patients with acute arthritis, osteoarthritis secondary to rheumatic diseases such as RA and gout, infectious arthritis, metabolic arthritis, traumatic arthritis, uncontrolled diabetes, known case of heart, liver, cancer  
Skin disease at the joint site  
Joint replacement through surgery  
Fiber myalgia, radiculopathy and neuropathy  
Patients taking glucosamine, chondroitin sulfate and muscle relaxants at the same time

#### Age

From **50 years** old to **80 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **92**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Randomization is done using random permutation blocks method. The size of the blocks is 4. Drugs in two categories (drug and diclofenac) are made by the study pharmacist and sent to the study statistics specialist. The statistician encodes them and places them in blocks of 4 (containing 2 numbers from each group). Unlock the codes will be done after the end of the study. In case of side effects, the drug code will be unlocked.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

ointment of pistacia Atlantica and diclofenac gel in cans with a single shape, with a similar label, will be prepared by a pharmacist in the laboratory of medicinal plants of the School of persian Medicine in Babol. It is then coded and blocked by a statistician and delivered to the researcher. The only person who knows the nature of the

cans is the pharmacist who makes the medicine.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

##### Street address

University Research Ethics Committee, Babol University of Medical Sciences, Ganj Afrooz Square, babol

##### City

Babol

##### Province

Mazandaran

##### Postal code

۴۷۱۷۶-۴۷۷۵۴

#### Approval date

2021-04-30, 1400/02/10

#### Ethics committee reference number

IR.MUBABOL.REC.1400.087

## Health conditions studied

### 1

#### Description of health condition studied

Primary osteoarthritis of the knee

#### ICD-10 code

M17

#### ICD-10 code description

Osteoarthritis of knee

## Primary outcomes

### 1

#### Description

Joint pain score in VAS questionnaire

#### Timepoint

At the beginning of the study (before the intervention) and 4 weeks after the start of treatment and 4 weeks after the end of treatment

#### Method of measurement

VAS questionnaire score

### 2

#### Description

Joint pain score in KOOS questionnaire

### **Timepoint**

At the beginning of the study (before the intervention) and 4 weeks after the start of treatment and 4 weeks after the end of treatment

### **Method of measurement**

KOOS questionnaire score

## **Secondary outcomes**

### **1**

#### **Description**

Joint symptoms score in the KOOS questionnaire

#### **Timepoint**

At the beginning of the study (before the intervention) and 4 weeks after the start of treatment and 4 weeks after the end of treatment

#### **Method of measurement**

Score in the KOOS questionnaire

### **2**

#### **Description**

Activity of daily live score in the KOOS questionnaire

#### **Timepoint**

At the beginning of the study (before the intervention) and 4 weeks after the start of treatment and 4 weeks after the end of treatment

#### **Method of measurement**

Score in the KOOS questionnaire

### **3**

#### **Description**

Sport

#### **Timepoint**

At the beginning of the study (before the intervention) and 4 weeks after the start of treatment and 4 weeks after the end of treatment

#### **Method of measurement**

Score in the KOOS questionnaire

### **4**

#### **Description**

Quality of life

#### **Timepoint**

At the beginning of the study (before the intervention) and 4 weeks after the start of treatment and 4 weeks after the end of treatment

#### **Method of measurement**

Score in the KOOS questionnaire

## **Intervention groups**

### **1**

#### **Description**

Intervention group: To prepare the medicine, pistacia Atlantica oil, which is traditionally oiled, is standardized and applied as ointment and packaged after standardization and quality control, under the

supervision of a traditional medicine pharmacist in the pharmacy laboratory of the Faculty of Persian Medicine. Patients who were randomly assigned to the intervention group after enrollment were given an ointment containing pistacia Atlantica oil to be applied topically around the knee three times a day for 4 weeks. Patients will be visited three times at the start of treatment, 4 weeks after starting treatment, and 4 weeks after stopping treatment, and will be evaluated for medication as well as possible side effects such as skin irritation and itching and allergy symptoms. And KOOS and VAS questionnaires will be completed.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: Patients in this group are given topical diclofenac gel in a package similar to the drug to be used topically around the knee up to three times a day for 4 weeks. Patients will be visited three times at the start of treatment, 4 weeks after starting treatment, and 4 weeks after stopping treatment, and will be evaluated for medication as well as possible side effects such as skin irritation and itching and allergy symptoms. And KOOS and VAS questionnaires will be completed.

#### **Category**

Placebo

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Babol Persian Medicine Health Center

##### **Full name of responsible person**

Fatemeh Azizi

##### **Street address**

next to the International Branch of the University and after Shahid Beheshti Hospital, Shahid Ghasemi St., Babol.

##### **City**

Babol

##### **Province**

Mazandaran

##### **Postal code**

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##### **Phone**

+98 11 3225 3526

##### **Email**

F.azizi@mubabol.ac.ir

##### **Web page address**

<https://tim.mubabol.ac.ir/page/?id=73>

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Reza Ghadimi

**Street address**

Vice Chancellor for Research and Technology, Babol  
University of Medical Sciences, Ganj Afrooz St., Babol

**City**

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**Province**

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**Postal code**

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**Phone**

+98 11 3219 0558

**Email**

research@mubabol.ac.ir

**Web page address**

<https://research.mubabol.ac.ir/about/?id=350>

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Babol 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**

Babol University of Medical Sciences

**Full name of responsible person**

Fatemeh Azizi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Faculty of persian Medicine, Babol University of  
Medical Sciences, Ganj Afrooz St., babol

**City**

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**Postal code**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Fatemeh Azizi

**Position**

Resident

**Latest degree**

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F.azizi@mubabol.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Fatemeh Azizi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

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**Phone**

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**Email**

F.azizi@mubabol.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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

Information about the main outcome can be shared.

### When the data will become available and for how long

Access period starts 6 months after the results are published

### To whom data/document is available

Researchers working in academic and scientific institutions

### Under which criteria data/document could be used

The conditions will be determined by the Faculty of Iranian Medicine of Babol University.

### From where data/document is obtainable

Fatemeh Azizi E-mail: F.azizi@mubabol.ac.ir

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

After receiving the e-mail from the researcher, the data request is reviewed by the Faculty of Iranian Medicine and the Vice Chancellor for Research and Technology, and if the requested information is approved, it will be provided to the individual.

### Comments