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
۴۷۱۷۶-۴۷۷۴۵
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
Babol

Province
Mazandaran

Postal code
۴۷۱۷۶-۴۷۷۴۵

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
Babol

Province
Mazandaran

Postal code
۴۷۱۷۶-۴۷۷۴۵

Phone
+98 11 3219 4730

Fax

Email
F.azizi@mubabol.ac.ir

Person responsible for scientific 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
Babol

Province
Mazandaran

Postal code
۴۷۱۷۶-۴۷۷۴۵

Phone
+98 11 3219 4730

Fax

Email
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

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

City
Babol

Province
Mazandaran

Postal code
۴۷۱۷۶-۴۷۷۴۵

Phone
+98 11 3219 4730

Fax

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