Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Assessment of the effect of jadwar capsule (delphinium denudatum) on clinical manifestation of knee Osteoartheritis versus Placebo : A double blind randomized controlled clinical trial.

Protocol summary

Study aim

Determination of the effects of Jadwar capsul on clinical manifestations of knee Osteoarthritis versus placebo

Design

Randomized controlled clinical trial with a parallel group design of 94 patient.phase 3.

Settings and conduct

Study will be performed in Tabriz Shohada hospital.Participants will be placed on intervention and control groups according block disign randomization method, after obtaining the informed consent and they will receive the drug or placebo for four weeks and thay will be under observation through this period.The study will be double-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 40 to 70 ; Mild to moderate knee Ostoarthritis patients according to Kellegren-Lawrence (K-L) grading scale ; Minimum annoying pain (at least 4) in last week before random allocation, according to VAS scale ; Pain at least in one knee in last 3 month ago. Exclusion criteria: Allergy to jadwar capsul ; Secondary osteoarthritis ; Joint transplantation ; Oral or topical use of steroids ; Pregnancy & lactation ; Addiction ; Radiculopathy or Neuropathy ; Surgery ; Trauma

Intervention groups

The intervention group received 500 mg jadwar capsules twice a day for four weeks each day.The control group received placebo capsules twice a day for four weeks. Pelacebo and jadwar Capsules are Produced in the shafanegar nazary pharmaceutical company.

Main outcome variables

1. Knee pain score according to Visual Analogue Scale and West Ontario McMaster universities questionaire 2. Daily activity score according to Visual Analogue Scale and West Ontario Mc master universities questionaire

General information

Reason for update

Updating the start and end date of patient recruitment has been accomplished

Acronym

IRCT registration information

IRCT registration number: **IRCT20181218042037N1**
Registration date: **2019-06-13, 1398/03/23**
Registration timing: **prospective**

Last update: **2020-06-12, 1399/03/23**
Update count: **1**

Registration date

2019-06-13, 1398/03/23

Registrant information

Name

Rogaiyeh Baghervandnavid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3382 6501

Email address

baghervandnavid@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-15, 1398/03/25

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

2019-06-15, 1398/03/25

Actual recruitment end date

2019-12-16, 1398/09/25

Trial completion date
2020-01-15, 1398/10/25

Scientific title
Assessment of the effect of jadwar capsule (delphinium denudatum) on clinical manifestation of knee Osteoartheritis versus Placebo : A double blind randomized controlled clinical trial.

Public title
Assessment of jadwar capsule on clinical manifestation of knee Osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Mild to moderate knee Ostoarthritis patients according to Kellegren-Lawrence (K-L) grading scale Pain at least in one knee in last 3 month ago Minimum annoying pain (at least 4) before randomized selection according to VAS scale

Exclusion criteria:
Allergy to oral consumption of jadwar capsul. Secondary Osteoarthritis as Rhuomatoid arthritis,Gout,Infectious arthritis,Metabolic arthritis,Traumatic arthritis. Operative knee joint replacement . Topical or systemic steroid use since 14 day before study . Intraarticular steroid injection since 90 day before study . Pregnancy and lactation period . Alcohol and opioid addiction Radiculopathy and Neuropathy . History of any kind of knee operation and trauma Utilization of other analgesic drugs since study period History of renal failure or heart failure or hepatic failure

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **94**
Actual sample size reached: **94**

Randomization (investigator's opinion)
Randomized

Randomization description
Block design randomization as individual by Random number table

Blinding (investigator's opinion)
Double blinded

Blinding description
participant clinical care provider researcher

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Of Tabriz University Of Medical Sciences

Street address
Tabriz University of Medical Sciences central building , Daneshgah Ave. , Tabriz

City
tabriz

Province
East Azarbaijan

Postal code
5165665931

Approval date
2019-03-12, 1397/12/21

Ethics committee reference number
IR.TBZMED.REC.1397.1054

Health conditions studied

1

Description of health condition studied
knee osteoarthritis

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Score of knee pain intensity

Timepoint
Measuring the Score of knee pain intensity at the beginning of the study and 14 and 28 days after starting use of jadwar capsul.

Method of measurement
Visual Analogue Scale

2

Description
Daily activity Score

Timepoint
Measuring of Daily activity Score at the beginning of the study and 14 and 28 days after starting use of jadwar capsul.

Method of measurement
Western Ontario and McMaster Universities Osteoarthritis questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group participants receive 500 m/g of jadwar capsul in the morning and at night for 4 weeks. jadwar Capsules are Produced in the shafanegar nazary pharmaceutical company.
Category
Treatment - Drugs

2

Description
Control group: In this group participants receive 2 placebo capsules containing starch in the morning and at night for 4 weeks. pelacebo Capsules will be Produced in the shefanegar nazary pharmaceutical company.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada hospital
Full name of responsible person
rogayeh baghervandnavid
Street address
Shohada hospital , Golshahr St., El-goli Ave
City
Tabriz
Province
East Azarbaijan
Postal code
5166614754
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+98 41 3389 3336
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baghervandnavid@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Abolghasem Jouyban
Street address
Golghasht Ave., No 2 Central Building of tabriz university of medical sciences
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East Azarbaijan
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5166616471
Phone
+98 41 3336 9798
Email
research-vice@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Rogayeh Baghervandnavid
Position
PhD candidate
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
No. 3, Alley 41, Goldasht St., Zafaranieh Ave.
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Rogaiyeh Baghervandnavid
Position

phd student

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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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

Not applicable

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The whole potential data after being unidentifiable is shareable

When the data will become available and for how long

Start the access period 4 months after printing the article

To whom data/document is available

Researchers working in academic, scientific and industrial institutions

Under which criteria data/document could be used

Additional conditions are not required.

From where data/document is obtainable

Rogayeh Babhervandnavid email baghervandnavd@tbzmed.ac.ir 09144082551 rbaghervand@hotmail.com

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

The requested files are submitted to the requestor about a week after receipt.

Comments