

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of edible traditional product” Dawa-e-balgham” on the pain of knee osteoarthritis patients with functional dyspepsia compared to the control group: randomized double-blind clinical trial

Protocol summary

Study aim

Evaluation of the effect of edible traditional product” Dawa-e-balgham” on the pain of knee osteoarthritis (KOA) patients with functional dyspepsia compared to the control group:

Design

This study is clinical Trial with randomized double blind parallel groups of Controlled and study one, and with a sample size of 100.

Settings and conduct

The trial will be conducted in a rheumatology clinic. The patients after inclusion, are divided into two intervention groups (based on having functional dyspepsia as a strata during randomization). All patients after 2 weeks wash out will be treated with oral medication by random sampling for 8 weeks. Participants, drug deliverers, outcome assessors, and data collectors were blind to the intervention group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: knee osteoarthritis diagnos according to American College of Rheumatology (ACR) criteria and signing patient consent form. Exclusion criteria: significant knee injury or surgery; knee pain related to other joint diseases; severe heart, liver and kidney disease.

Intervention groups

All patients receive oral capsule (500 mg) after each meal 3 times a day for 8 weeks. Patients in intervention group take Dawa-Balgham and in control group receive placebo.

Main outcome variables

Pain severity, The quality of patients' performance

General information

Reason for update

Acronym

اوستئوآرتریت زانو Knee osteoarthritis (KOA)

IRCT registration information

IRCT registration number: **IRCT20190807044470N1**

Registration date: **2019-11-27, 1398/09/06**

Registration timing: **prospective**

Last update: **2019-11-27, 1398/09/06**

Update count: **0**

Registration date

2019-11-27, 1398/09/06

Registrant information

Name

Fariba Hadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3346 0172

Email address

hadiyari1000@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-06, 1398/09/15

Expected recruitment end date

2020-08-31, 1399/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of edible traditional product”

Dawa-e-balgham" on the pain of knee osteoarthritis patients with functional dyspepsia compared to the control group: randomized double-blind clinical trial

Public title
Evaluation of the effect of edible traditional product" Dawa-e-balgham" on the pain of knee osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Knee pain at least one for most days of the prior month, in addition to at least 5 of the following 6: Crepitus on active joint motion Morning stiffness less than 30 minutes' duration Bony enlargement of the knee on examination Bony tenderness of the knee on examination No palpable warmth. Age older than 50 years Average pain on the Visual Analogue Scale (VAS) ≥ 30 out of 100 mm.
Exclusion criteria:
History of knee surgery Knee pain related to rheumatological disease or other conditions such as infectious diseases Pregnancy and breast feeding Presence of inflammatory rheumatic diseases Being treated with any of the complementary medicine the prior 3 month Self management of pain by sedatives and anti inflammatory drugs Using of corticostereoid less than last 5 weeks ago Intra-articular depo corticostereoid injection in less than 3 last months. Intra articular hyaluronate injection in less than past 6 months Arthroscopy in past one years history of Significant knee trauma in less than past 6 months Contraindication for paracetamol using history of severe cardiac, renal and liver disease Anticoagulant drugs using Worrying in heat and dryness

Age
From **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into two groups based on the problem of concurrent dyspepsia as strata after entering the study. Then, randomization is performed for each group using the permuted block randomization method, with patients block size of four. We use <https://www.sealedenvelope.com> to create a random sequence.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients, drug deliverers, clinical caregivers, data

collectors and outcome assessors are blind in study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran National Committee for Ethics in Biomedical Research

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2019-10-06, 1398/07/14

Ethics committee reference number

IR.TUMS.VCR.REC.1398.600

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

2

Description of health condition studied

Functional dyspepsia

ICD-10 code

K30

ICD-10 code description

Functional dyspepsia

Primary outcomes

1

Description

Pain severity score on the visual analogue scale

Timepoint

At baseline (before baseline) and 14 days later (at the

end of Wash out period) and at week 4, 8, 12, 16 after administration of prophylactic capsules.

Method of measurement

Visual analogue Scale

Secondary outcomes

1

Description

Functional dyspepsia severity score

Timepoint

At baseline (before baseline) and 14 days later (at the end of Wash out period) and at week 4, 8, 12, 16 after administration of prophylactic capsules.

Method of measurement

the Leeds Dyspepsia Questionnaire (LDQ)

2

Description

Quality of life score

Timepoint

At baseline (before baseline) and 14 days later (at the end of Wash out period) and at week 4, 8, 12, 16 after administration of prophylactic

Method of measurement

Knee injury and Osteoarthritis Outcome Score (KOOS)

3

Description

Diagnose of functional dyspepsia score

Timepoint

At baseline (before baseline)

Method of measurement

Rome III questionnaire

Intervention groups

1

Description

Intervention group 1: patients who receive oral capsule (500 mg) of Dawa-Balgham containing Nigella sativa L., Trachyspermum ammi, zataria multiflora and mastic (gum) after each meal 3 times a day for 8 weeks and if needed, acetaminophen tablets can take up to 1 gram every 6 hours. Then patients will be followed for 8 weeks for treatment outcomes. Patients will not be allowed to use acetaminophen during the follow-up period. The duration of the study is 16 weeks.

Category

Treatment - Drugs

2

Description

Control group: the patients who receive placebo containing 125 mili gram toast powder after each meal 3 times a day for 8 weeks and if needed, acetaminophen tablets can take up to 1 gram every 6 hours. Then

patients will be followed for 8 weeks for treatment outcomes. Patients will not be allowed to use acetaminophen during the follow-up period. The duration of the study is 16 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Fariba Hadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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
Tehran University of Medical Sciences
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Fariba Hadi
Position
Resident
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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

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

Information about the main outcome of this study will be shared through the article.

When the data will become available and for how long

The start of the access period will be 6 month after the results are printed.

To whom data/document is available

Researchers working in academia and academics and industry professionals

Under which criteria data/document could be used

For further studies in the treatment of knee osteoarthritis based on our study protocol

From where data/document is obtainable

Fariba Hadi: hadiyari1000@gmail.com

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

Written request by email one month after publication of the article

Comments