Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 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 rheumathology 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 hyaloronate 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

Street address

Shariati Hospital, Rheumatology Research Center, North Kargar Ave.

City

Tehran

Province

Tehran

Postal code

1411713137

Phone

+98 21 8822 0064

Email

hadiyari1000@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Mohammad Ali Sahraian

Street address

Sixth Floor,, Qods Ave., Keshavarz Blvd, Central Building of Tehran University of Medical Sciences, Vice Chancellor for Research

City

Tehran

Province

Tehran

Postal code

1416663361

Phone

+98 21 8163 3686

Fax

+98 21 8163 3687

Email

vcr@tums.ac.ir

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

Full name of responsible person
Fariba Hadi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

Street address
Faculty of Iranian Medicine, No. 27, North Supervisor Street, West Taleghani Ave.

City
Tehran

Province
Tehran

Postal code
141663361

Phone
009888974535

Email
hadiyari1000@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Fatemeh Nejatbakhsh

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Traditional Medicine

Street address
Faculty of Iranian Medicine, No. 27, North Supervisor Street, West Taleghani Ave.

City
Tehran

Province
Tehran

Postal code
141663361

Phone
+98 21 8897 4535

Email
Nejatbakhsh@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Fariba Hadi

Position
student

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

Street address
Faculty of Iranian Medicine, No. 27, North Sarparast Street, West Taleghani Ave.

City
Tehran

Province
Tehran

Postal code
1476774431

Phone
+98 21 4443 8632

Email
hadiyari1000@gmail.com

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