

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Comparison of efficacy of Pistacia atlantica L. oleoresin with that of placebo in treatment of patients with functional dyspepsia

Protocol summary

Study aim

Comparison of the effectiveness of Pistacia atlantica oleoresin and placebo in the treatment of functional dyspepsia patients

Design

Randomized; block randomization with computer generated random numbers table and sequentially numbered containers each representing a block consisting of ten patients are used for the treatment assignments; double-blind; controlled with placebo; two group parallel design; single-center; phase 3 of clinical trial. Study population: patients with functional dyspepsia. Sample size: 100 patients.

Settings and conduct

The trial setting: Baqiyatallah Hospital. Protocol: fifty patients use two 200 mg capsules of Pistacia atlantica oleoresin and 50 patients use two placebo capsules orally every 12 hours for 2 months. Before intervention and 2 months after intervention the groups' dyspepsia, Helicobacter pylori infection and quality of life are compared with each other. Blinding: three different persons generate the random allocation sequence, enroll the participants and assign them to intervention groups. These persons, care providers, outcome assessors, data analyzer, investigators and participants are blinded to assignment to the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 20 to 80; patients with functional dyspepsia according to the ROME III criteria; patients without organic, systemic and metabolic diseases causing dyspepsia. Exclusion criteria: pregnant women; women planning pregnancy; breast-feeding women.

Intervention groups

Fifty patients use two 200 mg Pistacia oleoresin capsules and 50 patients use two placebo capsules orally every 12 hours for 2 months.

Main outcome variables

Primary outcome variable: dyspepsia. Secondary

outcome variables: Helicobacter pylori infection, quality of life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090804002288N14**

Registration date: **2018-07-16, 1397/04/25**

Registration timing: **prospective**

Last update: **2018-07-16, 1397/04/25**

Update count: **0**

Registration date

2018-07-16, 1397/04/25

Registrant information

Name

Saeed Kianbakht

Name of organization / entity

Iranian Academic Center for Education, Culture and Research Institute of Medicinal Plants

Country

Iran (Islamic Republic of)

Phone

+98 26147640109

Email address

kianbakht@imp.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of Pistacia atlantica L. oleoresin with that of placebo in treatment of patients with functional dyspepsia

Public title

Effects of Pistacia atlantica oleoresin in treatment of functional dyspepsia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged 20 to 80 Patients with functional dyspepsia according to the ROME III criteria Patients without organic, systemic and metabolic diseases causing dyspepsia

Exclusion criteria:

Pregnant women Women planning pregnancy Breast-feeding women

Age

From **20 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: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with computer generated random numbers table and sequentially numbered containers each representing a block consisting of ten patients are used for the treatment assignments.

Blinding (investigator's opinion)

Double blinded

Blinding description

Three different persons generate the random allocation sequence, enroll the participants and assign them to intervention groups. These persons, care providers, outcome assessors, data analyzer, investigators and participants are blinded to assignment to the Pistacia atlantica oleoresin and placebo groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Avicenna Research Institute

Street address

Avicenna Resrach Institute, Shaheed Beheshti University, Darakeh Street

City

Tehran

Province

Tehran

Postal code

1936773493

Approval date

2018-01-16, 1396/10/26

Ethics committee reference number

IR.ACECR.Avicenna.REC.1396.22

Health conditions studied**1****Description of health condition studied**

Functional dyspepsia

ICD-10 code

K30

ICD-10 code description

Functional dyspepsia

Primary outcomes**1****Description**

Dyspepsia

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Hong Kong dyspepsia index questionnaire

Secondary outcomes**1****Description**

Quality of life

Timepoint

Before intervention and 2 months after intervention

Method of measurement

SF-36 questionnaire

2**Description**

Helicobacter pylori infection

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Urease test

3

Description

Adverse drug reactions

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Patient questioning

Intervention groups

1

Description

Intervention group: Pistacia atlantica oleoresin is administered to a group of 50 patients at the dose of two 200 mg capsules every 12 hours for 2 month.

Category

Treatment - Drugs

2

Description

Control group: Two placebo capsules are administered to another group of 50 patients every 12 hours for 2 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Dr. Reza Mohtashami

Street address

Molla Sadra street, Vanak square

City

Tehran

Province

Tehran

Postal code

1435915371

Phone

+98 21 8805 0435

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reza_mohtashami1979@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Dr. Reza Hajiaghaee

Street address

ACECR Complex, Supa Boulevard, Poleh Kordan

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Karaj

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3365166571

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Email

hajiaghaee@imp.ac.ir

Web page address

http://www.imp.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iranian academic center for education culture and research

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

Iranian academic center for education culture and research

Full name of responsible person

Dr. Saeed Kianbakht

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmacology

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Person responsible for scientific inquiries

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Iranian academic center for education culture and research

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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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All collected deidentified IPD are to be shared.

When the data will become available and for how long

Access period starting 6 months after publication for 1 year.

To whom data/document is available

Researchers working in university and scientific and industrial institutes.

Under which criteria data/document could be used

Only statistical analyses mentioned in the article resulting from the study for personal knowledge are permitted. Written request for access to data and documents and its aim must be certified by the highest ranking official of the work place of the requester.

From where data/document is obtainable

Dr. Saeed Kianbakht with the address ACECR Institute of Medicinal plants, P.O. Box: 31375-369, Iran.

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

Written request should be sent to the address Dr. Saeed Kianbakht, ACECR Institute of Medicinal Plants, P.O. Box: 31375-369, Iran. The documents or data file will be sent to the requester by email.

Comments