Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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+98 26147640109

Email address

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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
Email
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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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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Institute of Medicinal Plants, ACECR Complex, Supa Boulevard, Poleh Kordan
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Email
kianbakht@imp.ac.ir
Web page address
http://www.imp.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
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