

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

comparison of efficacy of pistacia atlantial oleoresin with that of placebo in treatment of patients with functional dyspepsia

Protocol summary

Study aim

comparison of efficacy of pistacia atlantial oleoresin with that of placebo in treatment of patients with functional dyspepsia in Baqiyatallah hospital in 2020

Design

Patients are randomly divided into two groups of 35. Famotidine tablets of 40 mg once daily are given to both groups. The other placebo is given in the same amount and in both forms of the drug in the form of tablets. Then, the patients are visited in the second and fourth weeks and the mentioned questionnaires are filled in each time. The study will be out

Settings and conduct

Patients are randomly divided into two groups of 35. Famotidine 40 mg tablets are given once a day to both groups. To one group coriander gum (0.9 g / day) per day and to the other group placebo of the same amount and both. The form of the drug is given in the form of tablets, then the patients are visited in the second and fourth weeks and the mentioned questionnaires are filled in each time. During this period, any unwanted side effects will be checked and if the patient does not tolerate, he will be excluded from the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Age 15 to 65 years Patients with ROME4 criteria including recurrent abdominal pain that recurs on average at least once a week for at least three months and abdominal pain associated with bowel movements and the frequency and appearance of bowel movements, any abdominal discomfort, any Abdominal discomfort species

Intervention groups

Famotidine 40 mg tablets are given to both groups once a day. One group is given coriander gum (0.9 g / day) per day and the other placebo is given the same amount and both forms of the drug as tablets.

Main outcome variables

Improves appetite, reduces nausea, reduces vomiting, reduces premature satiety.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210124050126N1**

Registration date: **2021-02-16, 1399/11/28**

Registration timing: **prospective**

Last update: **2021-02-16, 1399/11/28**

Update count: **0**

Registration date

2021-02-16, 1399/11/28

Registrant information

Name

Erfan Ashjaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 5503

Email address

dr.erfan.ashjaei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of efficacy of pistacia atlantial oleoresin with that of placebo in treatment of patients with functional dyspepsia

Public title

comparison of efficacy of pistacia atlantial oleoresin with that of placebo in treatment of patients with functional dyspepsia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 15 to 65 years, Patients with ROME4 criteria including recurrent abdominal pain that recurs on average at least once a week for at least three months abdominal pain associated with bowel movements and the frequency and appearance of bowel movements any abdominal discomfort, any Abdominal discomfort species

Exclusion criteria:

IBS, PUD, GERD CHF, DM, ATHMA, COPD and, , , , Psychological diseases history of alcohol and opium addiction ,gastrointestinal surgery need for continuous use of cardiological drugs antihypertensive antipsychotic sedatives antibiotics corticosteroids

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization
Randomization unit: individual Randomization tool:
Random number table

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiyatallah University of
Medical Sciences

Street address

Tehran, vanak

City

تهران

Province

Tehran

Postal code

1435915371

Approval date

2021-01-09, 1399/10/20

Ethics committee reference number

IR.BMSU.BAQ.REC.1399.045

Health conditions studied

1

Description of health condition studied

Functional dyspepsia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Flatulence, premature satiety, loss of appetite

Timepoint

2 and 4 weeks after starting to use L Pistacia atlantica
gum

Method of measurement

Hong Kong Questionnaire

Secondary outcomes

1

Description

Quality of Life

Timepoint

2 and 4 weeks after the onset of gum

Method of measurement

Quality of Life Questionnaire sf-36

Intervention groups

1

Description

In this study, two groups of 35 persons will participate, which is a control group, treated with 9 grams of mastic gum (0.9gr / day) per day in 3 divided doses with famotidine 40 mg tablet daily to be.

Category

Treatment - Drugs

2

Description

Control group: Control group: In this study, a control group consisting of 35 people receiving placebo

treatment with famotidine 40 mg will receive daily.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Baqiyatallah hospital
Full name of responsible person
morteza jodi chelansofla
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Tehran, Vanak
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
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Email
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah University of Medical Sciences
Proportion provided by this source
50
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

2

Sponsor

Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
معاونت پژوهش دانشگاه بقیه الله ع
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City
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Province
Tehran
Postal code
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Phone
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Email
saidejudi766@gmail.com
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Title of funding source
Bagheiat-allah University of Medical Sciences
Proportion provided by this source
50
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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
morteza jodi chelansofla
Position
general practitioner
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

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Name of organization / entity

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

erfan ashjaei

Position

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Latest degree

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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

Coded data will be provided

When the data will become available and for how long

After analyzing and printing the results

To whom data/document is available

The main executors of the project

Under which criteria data/document could be used

With the permission of the person in charge of the project and at the request of the higher authorities to verify the data

From where data/document is obtainable

Project Manager

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

Send an email to the scientific manager of the project and make a request with him

Comments