

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 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

**Street address**

Tehran, Vanak

**City**

tehran

**Province**

Tehran

**Postal code**

1435915371

**Phone**

+98 41 3740 5295

**Email**

saidejudi766@gmail.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

morteza jodichelansofla

**Street address**

Tehran, vanak

**City**

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**Province**

Tehran

**Postal code**

1435915371

**Phone**

+98 41 3740 5295

**Email**

saidejudi766@gmail.com

**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

**Street address**

tehran, vanak, baqiyatallah university

**City**

tehran

**Province**

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**Postal code**

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**Phone**

+98 41 3740 5295

**Email**

saidejudi766@gmail.com

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

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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

**Street address**

tehran vanak

**City**

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**Province**

Tehran

**Postal code**

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**Phone**

+98 41 3740 5295

**Email**

saidejudi766@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

morteza jodi chelansolfa

**Position**

general practioner

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

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**City**

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**Province**

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**Postal code**

1435915371

**Phone**

+98 41 3740 5295

**Email**

saidejudi766@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

erfan ashjaei

**Position**

general practioner

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

tehran vanak

**City**

tehran

**Province**

Tehran

**Postal code**

1435915371

**Phone**

+98 21 2676 3281

**Email**

dr.erfan.ashjaei@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**

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**