

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the efficacy of topical Pistacia lentiscus oil in patients with functional dyspepsia

#### Protocol summary

##### Study aim

Determination of the efficacy of Mastic oil on symptoms of dyspepsia symptoms in patients with functional dyspepsia

##### Design

Clinical trials with control group, with parallel groups, triple-blind, randomized

##### Settings and conduct

questionnaire Imam Khomeini Hospital

##### Participants/Inclusion and exclusion criteria

Criteria for inclusion in the study include: The existence of functional dyspepsia symptoms based on ROMVI criteria ; Functional Dyspepsia with the overcoming of the sign: postprandial fullness and early satiation ; Both sexes ; Aged 18 to 60 years ; Negative Helicobacter pylori (determined by endoscopy) ; Written informed consent Non-inclusion criteria include: Dyspepsia with overwhelming heartburn symptoms ; Alert symptoms: Progressive weight loss without diet, Gastrointestinal bleeding in the form of blood vomiting, ricket stool, or iron deficiency anemia, progressive dysphagia (dysphagia) or painful ingestion (oedinophagia), repeated vomiting or food back, abdominal mass, lymphadenopathy or ascites ; Family history of gastric cancer in relatives of first degree relatives ; IBD ; Duodenitis ; Gastritis ; Peptic ulcer ; Reflux (the most important complaint) ; Taking NSAIDs or corticosteroids for more than a month ; GI outlet blockage on endoscopy ; GI malignancy ; History of gastric surgery ; Pregnancy and lactation ; Chronic diseases of the heart, kidney, liver, gallbladder ; Diabetes, and other metabolic diseases that cause dyspepsia. ; Smoking and Alcohol consumption ; BMI higher than 30 ; Use of other herbal chemicals for Disopecia

##### Intervention groups

The Intervention group 1: Mastic oil group, patients in this group consume Mastic oil. The intervention group 2: The placebo group, patients in this group take placebo.

##### Main outcome variables

Severity of functional dyspepsia symptoms

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20090527001957N8**

Registration date: **2019-08-22, 1398/05/31**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-26, 1398/10/05**

Update count: **1**

##### Registration date

2019-08-22, 1398/05/31

##### Registrant information

##### Name

Fataneh Hashem Dabaghian

##### Name of organization / entity

Research Institute for Islamic and Complementary Medicine

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3395 0152

##### Email address

fatanehdabaghian@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-16, 1398/01/27

##### 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**  
Evaluation of the efficacy of topical Pistacia lentiscus oil in patients with functional dyspepsia

**Public title**  
Effect of Pistacia lentiscus in functional dyspepsia

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Negative H. pylori infection in endoscopy Occurrence of functional Dyspepsia based on ROME IV criteria Written informed consent Possibility of patient tracking  
**Exclusion criteria:**  
IBD disease Esophagitis, gastritis, duodenitis Gastric ulcer, gastrointestinal bleeding Reflux (the most important complaint) Gastrointestinal outlet obstruction in the endoscopy Gastrointestinal malignancy or gastric malignancy in first-degree relative affinity History of gastric surgery Chronic diseases of the heart, kidney, liver, gallbladder Diabetes and other metabolic diseases that cause dyspepsia Iron deficiency anemia Progressive Weight Loss Without Diet BMI higher than 30, pregnancy or intent to be pregnant and breastfeeding Smoking and alcohol consumption Taking NSAIDs or corticosteroids for more than a month Consumption of other herbal medicines, chemical for Dyspepsia Dyspepsia caused by drugs

**Age**  
From **18 years** old to **60 years** old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Blocks randomization method is used and blocks are randomly selected by using the table of random numbers. Allocation concealment will be carried out using sealed envelopes.

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
Mastic oil and placebo are prepared in similar containers. Therefore, the participants during the trial, data collectors, outcome assessors, analyser and authors of the article are not aware of the type of drug and

placebo.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Ethics Committee of Research of the Faculty of Pharmacy and Pharmaceutical Sciences, Islamic Azad Un  
**Street address**  
Headquarters of the Ministry of Health and Medical Education, Iran's Simay Avenue, between South Falamak and Zarafshan, Ghods Town, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1467664961

**Approval date**  
2018-12-30, 1397/10/09

**Ethics committee reference number**  
IR.IAU.PS.REC.1397.322

**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**  
Severity of Dyspepsia symptoms

**Timepoint**  
Before the intervention, the end of the first month

**Method of measurement**  
One and two Dyspepsia questionnaire

**Secondary outcomes**

## 1

### Description

early satiation, postprandial fullness

### Timepoint

at the beginning and the end of the study

### Method of measurement

checklist of symptoms

## Intervention groups

### 1

#### Description

First intervention group: Mastic oil, which is made from a combination of 134 grams of Mastic gum and 536 grams of Sesame oil, topically applied three times a day after meals, and each time 10 drops are applied to the epigastric area for 4 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

The second intervention group: Placebo containing only Sesame oil, which is taken topically 3 times a day after meals, and 10 drops per episode area for 4 weeks each time.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini gastroenterology center

##### Full name of responsible person

Mahsa Baradaran sattarzadeh

##### Street address

End of Keshavarz Boulevard, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

##### Phone

+98 21 2277 3592

##### Email

mahsa.baradaran28@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research Institute for Islamic and Complementary  
Medicine

##### Full name of responsible person

Ali Ghobadi

##### Street address

No: 9, pirnia alley, lalehzar st, jomhuri Ave, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1145847111

##### Phone

+98 21 3345 0154

##### Email

alighobadi56@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Research Institute for Islamic and Complementary  
Medicine

#### 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

Research institute for Islamic and Complementary  
Medicine

##### Full name of responsible person

Fataneh Hashem-Dabaghian

##### Position

Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Community medicine

##### Street address

No:9, Pirnia Alley, lalehzar st, jomhuri Ave, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1145847111

##### Phone

+98 21 3395 0154

##### Fax

##### Email

fataneh.dabaghian@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Research Insstitute for Islamic and Complementary  
Medicine

**Full name of responsible person**

Fataneh Hashem Dabaghian

**Position**

community medicine specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Community assistance

**Street address**

9 pirnia alley, Lalehzar st.,Jomhury st.,Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1145847111

**Phone**

+98 21 3311 1619

**Fax****Email**

fatanehdabaghian@yahoo.com

**Web page address**

Specialist

**Other areas of specialty/work**

Community medicine

**Street address**

9Pirnia,Lalehzarno st,Jomhury Av,Tehran,Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1145847111

**Phone**

+98 33111619

**Fax****Email**

fataneh.dabaghian@yahoo.com

**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

## Person responsible for updating data

### Contact

**Name of organization / entity**

Research Institute For Islamic &Complementary  
Medicine

**Full name of responsible person**

Fataneh Hashem Dabaghian

**Position**

Assistant professor

**Latest degree**