

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)

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+98 21 3395 0152

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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

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End of Keshavarz Boulevard, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Institute for Islamic and Complementary
Medicine

Full name of responsible person

Ali Ghobadi

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

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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

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

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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
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Full name of responsible person

Fataneh Hashem Dabaghian

Position

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Latest degree