Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Iran (Islamic Republic of)

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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

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