Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of Melissa officinalis capsules on functional dyspepsia: a clinical trial study

Protocol summary

Study aim
Investigating the effect of lemon balm capsules on functional dyspepsia

Design
A controlled clinical trial, three-way blinded, randomized using block design, with a sample size of 43 individuals in each group.

Settings and conduct
Patients referred to the medical treatment centers of Mashhad University of Medical Sciences who are diagnosed with functional dyspepsia according to the Rome IV diagnostic criteria by a specialist will be included in the study and will be randomly divided into two groups: the treatment group and the control group. In the treatment group, a capsule containing 500 mg of Melissa officinalis, approved by the Ministry of Health, is prescribed twice a day after meals, with one capsule per dose. The standardization of this capsule is based on a minimum of 6 mg of rosmarinic acid in each capsule. In the control group, patients take a placebo capsule twice a day in the same manner.

Participants/Inclusion and exclusion criteria
Entry criteria: Individuals who have had gastrointestinal symptoms based on Rome IV criteria in the past 6 months, lasting at least three months and without structural diseases of the stomach. These criteria include: bloating or fullness after eating, early satiety, epigastric pain, or heartburn.Exclusion criteria: Organic gastrointestinal disorders, metabolic disorders, hypercalcemia, heavy metal poisoning, gastroparesis, diabetic radiculopathy, parasites (Giardia, Strongyloides), hepatoma, and pregnant and breastfeeding mothers, hypothyroidism.

Intervention groups
Intervention group: Capsule containing 500 mg of lemon balm powder, twice a day for 4 weeks. Control group: Capsule containing 500 mg of Avicel, twice a day for 4 weeks.

Main outcome variables
The severity of dyspepsia symptoms, quality of life, symptoms of gastric and general malaise, symptoms of depression and anxiety.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250816066868N1**
Registration date: **2025-12-06, 1404/09/15**
Registration timing: **registered_while_recruiting**

Last update: **2025-12-06, 1404/09/15**
Update count: **0**

Registration date
2025-12-06, 1404/09/15

Registrant information

Name
Batoul Heydari yazdi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3879 0642

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heidarib1@mums.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-09-23, 1404/07/01

Expected recruitment end date
2027-09-23, 1406/07/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Melissa officinalis capsules on functional dyspepsia: a clinical trial study

Public title

Investigating the effect of Melissa officinalis capsules on functional dyspepsia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals with functional dyspepsia (according to Rome IV criteria) who have completed the informed consent form and meet the inclusion criteria without meeting the exclusion criteria will be included in the study.

Exclusion criteria:

Patients with organic digestive disorders include: peptic ulcer, malignancies of the digestive tract, gallbladder-related pain, celiac disease, chronic pancreatitis, Crohn's disease, eosinophilic gastroenteritis, infiltrative stomach diseases (such as sarcoidosis, lymphoma, and amyloidosis), as well as metabolic disorders, hypercalcemia, heavy metal poisoning, gastroparesis, diabetic radiculopathy, parasites (Giardia, Strongyloides), hepatomegaly, and pregnant and breastfeeding mothers, hypothyroidism.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

To ensure equal and completely random distribution of participants in the groups, the randomization process will be carried out entirely through the online system https://www.sealedenvelope.com. To randomly assign individuals to two groups A and B in a 1:1 ratio, a block randomization method with sizes of 4 and 6 will be used, so that a total of 94 participants will be randomly distributed between the two groups through 13 blocks of 4 and 7 blocks of 6.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients were randomly assigned to receive either the drug or placebo, which were packaged identically and provided to the researcher after coding (in blocks of four and six). Statistical analysis will be conducted by an individual who is unaware of the intervention groups. Allocation concealment has also been maintained.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

No.149 ,Nofel Loshato 14/1

City

Mashhad

Province

Razavi Khorasan

Postal code

9177643735

Approval date

2025-05-14, 1404/02/24

Ethics committee reference number

IR.MUMS.REC.1404.041

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 score of dyspeptic symptoms

Timepoint

4 times: upon arrival, after 2, 4, and 8 weeks.

Method of measurement

GIS Dyspepsia Symptom Severity Questionnaire

Secondary outcomes

1

Description
Quality of life
Timepoint
3 times: upon arrival, after 4 and 8 weeks
Method of measurement
Quality of Life Questionnaire in Dyspepsia (NDI)

2

Description
Symptoms of depression and anxiety
Timepoint
4 times: upon arrival, after 2, 4, and 8 weeks.
Method of measurement
Hamilton Depression and Anxiety Questionnaire

3

Description
General temperamental symptoms
Timepoint
At the beginning of the study and week 4
Method of measurement
Doctor Mojahidi's temperament questionnaire

4

Description
Symptoms of stomach disorders
Timepoint
At the beginning of the study and week 4
Method of measurement
Stomach temperament questionnaire by Dr. Hosseinzadeh

Intervention groups

1

Description
Intervention group:: A capsule containing 500 mg of lemon balm powder, taken twice a day after meals, for a duration of 4 weeks.
Category
Treatment - Drugs

2

Description
Control group: Capsule containing 500 mg of Avicel, twice a day after meals, for a duration of 4 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Traditional Medicine Clinic of Imam Reza Hospital
Full name of responsible person
Fatemeh Mahjoob
Street address
Imam Reza Hospital, University Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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Research and Technology Department, Qureshi Building, University Street
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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
Mashhad University of Medical Sciences
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
Mashhad University of Medical Sciences

Full name of responsible person
Batool Heydari Yazdi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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Fatemeh Mahjoub

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Assistant Professor, MD, Ph.D

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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Associate professor

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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