Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Assessment of effect of Wild Mint product in Postprandial Distress Syndrome

Protocol summary

Summary

Functional dyspepsia (FD) is characterized by a high prevalence rate and no standard conventional treatments which causes a significant reduction in the quality of life. Alternative therapies, such as herbal formulas, are widely used to treat FD. In Traditional Iranian medicine, Wild Mint (SN: Mentha Longifolia؛ LN: Pune) has long been one of the most frequently prescribed for treating dyspepsia and bloating. The current study is designed to evaluate the efficacy and safety of Wild Mint for FD patients. Methods: This randomized, double-blind, placebo-controlled trial will be performed at one center and will include A Wild Mint capsule group and placebo (corn) group. Each group will consist of 50 FD patients . four weeks of administration of Wild Mint or placebo will be conducted. During the subsequent 2 months, follow-up observations of primary and secondary outcomes will be performed. The primary outcomes are differences as measured on the gastrointestinal symptom scale, and the secondary outcomes are differences as measured on the visual analogue scale for dyspepsia and on the questionnaire for FD-related quality of life. All outcomes will be measured at baseline, at 2, 4 weeks of treatment, and at the 2 month follow-up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013043013183N1**
Registration date: **2013-06-03, 1392/03/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-06-03, 1392/03/13

Registrant information

Name
Mahmoud Babaeian
Name of organization / entity
Shahed University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source
Shahed University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of effect of Wild Mint product in Postprandial Distress Syndrome

Public title

Effect of Wild Mint product in Postprandial Distress Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with 18-65 old years؛ Early Satiety؛ bothersome postprandial fullness؛ Without Organic Disorders on physical examination and Endoscopic Exclusion criteria: Patients with organic

disorders؛ The use of Chemicals and Herbals any other medication؛ History of Abdominal surgeries؛ History of bloody diarrhea؛ Pregnancy and lactation؛ Lack of interest in work؛ Not sign the consent

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
NO

Secondary trial Id
NO

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahed University of Medical Sciences

Street address
Abdolahzadeh Ave؛ Tehran

City
Tehran

Postal code

Approval date
2013-04-10, 1392/01/21

Ethics committee reference number
41/1681152

Health conditions studied

1

Description of health condition studied
Dyspepsia

ICD-10 code
K30

ICD-10 code description
Indigestion

Primary outcomes

1

Description
Severity Assessment of Dyspepsia

Timepoint
At baseline,at 2,4,12 weeks

Method of measurement
The Gastrointestinal Symptom Scale

2

Description
Quality of life

Timepoint
At Baseline؛ at 12 Weeks

Method of measurement
SF-36 Questionnaire

Secondary outcomes

1

Description
Side Effects

Timepoint
During the 12-week follow-up study

Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Wild Mint Capsules 500 mg؛ For 4 weeks؛ Three times daily after meals

Category
Treatment - Drugs

2

Description
placebo: Corn starch Capsules 500 mg؛ For 4 weeks، Three times a daily after meals

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Digestive Health Center

Full name of responsible person

Mahmoud Babaeian. MD
Street address
Shariati Ave.؛ Hakim Nezami Ave.
City
Isfehan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
shahed University of Medical Sciences
Full name of responsible person
Mohsen Naseri.MD
Street address
Traditional Medicine Clinical Trial Research Center؛ No.1471 ؛ Between Forsat and Nosrat Ave؛ North Kargar Ave؛ Enghelab Ave.
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
shahed University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary

empty