

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 21 6641 2313

Email address

drbabaeian@yahoo.com

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

Abdolazadeh 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

Isfahan

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.

City

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

Shahed University of Medical Sciences

Full name of responsible person

Mahmoud Babaeian

Position

Resident ph.D of Iranian Traditional Medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Resident of Ph.D Iranian Traditional Medicine

Other areas of specialty/work

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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