

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of efficacy of *Mentha pulegium* L. with that of placebo in treatment of patients with functional dyspepsia

Protocol summary

Summary

Objective: comparison of efficacy of *Mentha pulegium* L. with that of placebo in treatment of patients with functional dyspepsia. Study design: randomized, double-blind, placebo-controlled, two group parallel design, single-center, phase 2 of clinical trial. Study population: patients with functional dyspepsia attending Baqiyatallah Hospital (Tehran, Iran). Inclusion criteria: patients aged 20 to 80; patients with functional dyspepsia according to the ROME III criteria; patients in whom upper gastrointestinal endoscopy has not shown any organic causes of dyspepsia; patients without organic, systemic and metabolic diseases causing dyspepsia. Exclusion criteria: patients with peptic ulcer disease, inflammatory bowel disease, irritable bowel syndrome, pure gastro-esophageal reflux disease and any organic gastrointestinal disease; patients with a history of *Helicobacter pylori* infection eradicating drugs use within the past 3 months; patients with a history of gastrointestinal system surgery; patients with background systemic diseases such as diabetes mellitus, heart failure, hepatic failure, renal failure, asthma, chronic obstructive pulmonary disease, neoplasms and severe psychiatric diseases; patients addicted to alcohol and opium; patients using cardiac, antihypertensive, antipsychotic, antianxiety, antibiotic and corticosteroid drugs and iron and calcium; patients with a history of discontinuing prescribed pharmacotherapy and incomplete treatment; pregnant women; women planning pregnancy; breast-feeding women. Sample size: 100 patients. Interventions: pennyroyal leaf extract is administered to a group of about 50 patients at the dose of one 330 mg capsule every 8 hours for 2 months and placebo capsule is administered to another parallel group of about 50 patients every 8 hours for 2 months. Before intervention and 2 months after intervention, the primary and secondary outcome variables are evaluated. Primary outcome variable: dyspepsia. Secondary outcome variables: *Helicobacter pylori* infection, quality

of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602172288N9**

Registration date: **2016-04-08, 1395/01/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-08, 1395/01/20

Registrant information

Name

Saeed Kianbakht

Name of organization / entity

Iranian Academic Center for Education, Culture and Research Institute of Medicinal Plants

Country

Iran (Islamic Republic of)

Phone

+98 26147640109

Email address

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Recruitment status

Recruitment complete

Funding source

ACECR Institute of Medicinal Plants

Expected recruitment start date

2015-12-21, 1394/09/30

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of efficacy of Mentha pulegium L. with that of placebo in treatment of patients with functional dyspepsia

Public title
Effects of pennyroyal in treatment of functional dyspepsia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patients aged 20 to 80; patients with functional dyspepsia according to the ROME III criteria; patients in whom upper gastrointestinal endoscopy has not shown any organic causes of dyspepsia; patients without organic, systemic and metabolic diseases causing dyspepsia. Exclusion criteria: patients with peptic ulcer disease, inflammatory bowel disease, irritable bowel syndrome, pure gastro-esophageal reflux disease and any organic gastrointestinal disease; patients with a history of Helicobacter pylori infection eradicating drugs use within the past 3 months; patients with a history of gastrointestinal system surgery; patients with background systemic diseases such as diabetes mellitus, heart failure, hepatic failure, renal failure, asthma, chronic obstructive pulmonary disease, neoplasms and severe psychiatric diseases; patients addicted to alcohol and opium; patients using cardiac, antihypertensive, antipsychotic, antianxiety, antibiotic and corticosteroid drugs and iron and calcium; patients with a history of discontinuing prescribed pharmacotherapy and incomplete treatment; pregnant women; women planning pregnancy; breast-feeding women.

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
2

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
Block randomization with computer generated random numbers table and sequentially numbered containers each representing a block consisting of two patients are

used for the treatment assignments.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Baqiyatallah University of Medical Sciences

Street address

Molla Sadra street, Vanak square

City

Tehran

Postal code

1435915371

Approval date

2015-12-20, 1394/09/29

Ethics committee reference number

IR.BMSU.REC.1394.149

Health conditions studied

1

Description of health condition studied

Dyspepsia

ICD-10 code

K30

ICD-10 code description

Dyspepsia

Primary outcomes

1

Description

Dyspepsia

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Hong Kong dyspepsia index questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

Before intervention and 2 months after intervention

Method of measurement

SF-36 questionnaire

2

Description

Helicobacter pylori infection

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Urease test

3**Description**

Adverse drug reactions

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Patient questioning

Intervention groups**1****Description**

Pennyroyal leaf extract is administered to a group of about 50 patients at the dose of one 330 mg capsule every 8 hours for 2 month.

Category

Treatment - Drugs

2**Description**

one placebo capsule is administered to another group of about 50 patients every 8 hours for 2 months.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Baqiyatallah Hospital

Full name of responsible person

Dr. Reza Mohtashami

Street address

Molla Sadra street, Vanak square

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for research of ACECR Institute of Medicinal Plants

Full name of responsible person

Dr. Reza Hajiaghaee

Street address

ACECR Complex, Supa Boulevard, Poleh Kordan

City

Karaj

Grant name

1892

Grant code / Reference number

1892

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of ACECR Institute of Medicinal Plants

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**

ACECR Institute of Medicinal Plants

Full name of responsible person

Dr. Saeed Kianbakht

Position

Ph.D. in pharmacology, assistant professor of the department of pharmacology and applied medicine in

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Phone**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