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

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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
Tehran

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
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Person responsible for updating data

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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