# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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**
kianbakht@imp.ac.ir


**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**
Ph.D. in pharmacology, assistant professor of the department of pharmacology and applied medicine in
**Other areas of specialty/work**
**Street address**
Institute of Medicinal Plants, ACECR Complex, Supa Boulevard, Poleh Kordan
**City**
Karaj
**Postal code**
**Phone**
+98 26 3476 4010
**Fax**
**Email**
skianbakht@yahoo.com; kianbakht@imp.ac.ir
**Web page address**

## Person responsible for scientific 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
**Other areas of specialty/work**
**Street address**
ACECR Complex, Supa Boulevard, Poleh Kordan
**City**
Karaj
**Postal code**

**Phone**
+98 26 3476 4010
**Fax**
**Email**
skianbakht@yahoo.com; kianbakht@imp.ac.ir
**Web page address**

## Person responsible for updating data

**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
**Other areas of specialty/work**
**Street address**
ACECR Complex, Supa Boulevard, Poleh Kordan
**City**
Karaj
**Postal code**
2378965473
**Phone**
+98 264734010
**Fax**
+98 26 3476 4021
**Email**
skianbakht@yahoo.com; kianbakht@imp.ac.ir
**Web page address**
www.imp.ac.ir

## 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*