# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Study on efficacy of honey based formulation of Nigella sativa seed oil in treatment of functional dyspepsia: A double blind randomized controlled clinical trial

## Protocol summary


**Summary**

This study aimed to evaluate the efficacy of Nigella sativa seed oil mixed with honey in treatment of patients with functional dyspepsia. Seventy patients diagnosed as functional dyspepsia according to ROME III criteria and confirmed by upper gastrointestinal endoscopy were selected and randomly divided in to two equal groups. Patients with organic causes of dyspepsia, peptic ulcer disease, inflammatory bowel disease or pure gastroesophageal reflux disease were excluded from the study. Patients in both groups were instructed to take 5 ml of Nigella sativa seed oil mixed with honey or placebo, 3 times per day after their meal. Patients in both groups also received 40 mg famotidine drug daily during the study.The dyspepsia severity as a primary out come and presence of H. pylori infection and different domains of health survey as secondary outcome were determined in both groups prior to and following 8 weeks of the intervention.


## General information

**Acronym**

-

**IRCT registration information**

IRCT registration number: **IRCT201505031157N11**
Registration date: **2015-06-03, 1394/03/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2015-06-03, 1394/03/13

**Registrant information**

**Name**

Hasan Fallah Huseini

**Name of organization / entity**

Institute of Medicinal Plants

**Country**

Iran (Islamic Republic of)

**Phone**

+98 26 3476 4010

**Email address**

fallah@imp.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research, Institute of Medicinal Plants

**Expected recruitment start date**

2014-04-01, 1393/01/12

**Expected recruitment end date**

2014-11-01, 1393/08/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Study on efficacy of honey based formulation of Nigella sativa seed oil in treatment of functional dyspepsia: A double blind randomized controlled clinical trial

**Public title**

Efficacy of Nigella sativa seed oil in treatment of functional dyspepsia

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Patients with clinical diagnosis of functional dyspepsia. Exclusion criteria: Patients with organic causes of dyspepsia; peptic ulcer disease; inflammatory bowel disease; pure gastroesophageal

reflux disease; incomplete or discontinuation of treatment functional dyspepsia; patients with a history of taking H. pylori eradicating medication in previous 3 months; any gastrointestinal surgery; clinical history of any underlying disease such as coronary heart disease, diabetes mellitus, asthma, cancer, and chronic obstructive pulmonary disease; taking medication such as antihypertensive drugs, corticosteroids and supplements such as iron and calcium.

**Age**
No age limit

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **70**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Baqiyatallah University of Medical Sciences

**Street address**
Tebo-o-Din Center, Vanak squer, Molasadra Ave

**City**
Tehran

**Postal code**
1484958693

**Approval date**
2010-12-12, 1389/09/21

**Ethics committee reference number**
22-340/s

## Health conditions studied

### 1

**Description of health condition studied**
Diseases of the digestive system

**ICD-10 code**
K30

**ICD-10 code description**
Dyspepsia

## Primary outcomes

### 1

**Description**
Functional dyspepsia

**Timepoint**
At starting of the study and after 8 weeks

**Method of measurement**
Functional dyspepsia was measured according to ROME III criteria and confirmed by upper gastrointestinal endoscopy

## Secondary outcomes

### 1

**Description**
Helicobacter pylori infection

**Timepoint**
At starting of the study and after 8 weeks

**Method of measurement**
Helicobacter pyloril infection was determined in laboratory by commercial urease test kit

### 2

**Description**
Health survey

**Timepoint**
At starting of the study and after 8 weeks

**Method of measurement**
Health survey was determined according to standared health survey short form (SF-36)

## Intervention groups

### 1

**Description**
Intervention group: 5 ml herbal drug (Mixture of Nigella sativa oil, honey and water in equaled proportion) administered 3 times a day orally for 8 week

**Category**
Treatment - Drugs

### 2

**Description**
Placebo group: 5 ml placebo (Mixture of mineral oil, honey and water in equaled proportion) administered 3 times a day orally for 8 week

**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Gastroentrology and Liver diseases research center, Baqiyatallah University of Medical Sciences
**Full name of responsible person**
Reza Mohtashami
**Street address**
Vanak squer, Molasadra Ave
**City**
Tehran

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice chancellor for research, Institute of Medicinal Plants
**Full name of responsible person**
Reza Hajiaghaee
**Street address**
Tehran-Qazwain Highway Research City Kavosh, Jahad daneshgahi research society
**City**
Karaj
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice chancellor for research, 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**
Institute of Medicinal Plants
**Full name of responsible person**
Hasan Fallah Huseini
**Position**
Ph.D. in Pharmacology
**Other areas of specialty/work**
**Street address**
Research Complex of Jahad Daneshgahi, Kavosh Boulevard, Supa Boulevard, 55th km of Tehran-Qazvin Highway
**City**
Karaj
**Postal code**
13601360
**Phone**
+98 263476401020
**Fax**
+98 34764021
**Email**
huseini_fallah@yahoo.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Gastroentrology and liver diseases research center, Baqiyatallah University of Medical Sciences
**Full name of responsible person**
Mohtashami Reza
**Position**
MD Internists
**Other areas of specialty/work**
**Street address**
Vanak Squer, Molasadra Ave
**City**
Tehran
**Postal code**
1484958693
**Phone**
+98 26 8806 8923
**Fax**
+98 88068923
**Email**
Reza_mohtashami1979@yahoo.com
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Institute of Medicinal Plants
**Full name of responsible person**
Hasan Fallah Huseini
**Position**
Ph.D. in Pharmacology
**Other areas of specialty/work**
**Street address**
Research Complex of Jahad Daneshgahi, Kavosh Boulevard, Supa Boulevard, 55th km of Tehran-Qazvin Highway
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+98 34764021
**Email**
huseini_fallah@yahoo.com
**Web page address**

## 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*