

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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 outcome 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 pylori 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**

Gastroentrolgy 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

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**Postal code**

13601360

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+98 263476401020

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huseini\_fallah@yahoo.com

**Web page address**

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Gastroentrolgy 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**

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### 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

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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*