

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

Gastroentrolology 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

Gastroentrolology 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

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+98 263476401020

Fax

+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