

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of "Dosin" with triple therapy in eradication of helicobacter pylori infection in patients with helicobacter pylori infection and functional dyspepsia: A Randomized Controlled Clinical Trial.

Protocol summary

Summary

Mixture of "Dosin" is a combination of Nigella sativa seeds and honey that has been advised in Islamic medicine to subside abdominal pain, bloating, nausea and anorexia. The main objective of this study is to compare the effect of "Dosin" with triple therapy in eradication of helicobacter pylori infection. At first, a pilot study on 10 patients with H. pylori infection and functional dyspepsia will be conducted. Diagnosis of infection is based on Urea Breath Test (UBT). Diagnosis of functional dyspepsia is based on one or more of the following symptoms in the absence of organic diseases: a burning sensation or discomfort in the upper abdomen or lower chest, sometimes relieved by food or antacids, early satiation and bothersome postprandial fullness. They will take mixture of "Dosin" 1 teaspoon/tds for 14 days by mouth. UBT will be repeated 4 weeks after the end of intervention. If "Dosin" can eradicate H. pylori in more than 60 % of cases, the next phase of study will be conducted. At this stage, ninety patients with H. pylori infection and dyspepsia will be allocated in 3 groups randomly. Patients in the first group will take mixture of "Dosin" 1 teaspoon/tds for 14 days by mouth. Patients in the second group will take Amoxicillin 1 g/bd, clarithromycin 500 mg/bd and pantoprazole 20 mg/bd for 14 days by mouth. Patients in the third group will take mixture of "Dosin" 1 teaspoon/tds , pantoprazole(20 mg/bd) for 14 days by mouth. The second UBT will be repeated four weeks after the end of interventions. Three groups will be compared for H. pylori eradication rate and symptoms of dyspepsia

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201209041957N3**

Registration date: **2012-09-24, 1391/07/03**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-09-24, 1391/07/03

Registrant information

Name

Fataneh Hashem Dabaghian

Name of organization / entity

Research Institute for Islamic and Complementary Medicine

Country

Iran (Islamic Republic of)

Phone

+98 21 3395 0152

Email address

fatanehdabaghian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Research Institute for Islamic and Complementary Medicine, Tehran University of Medical Sciences

Expected recruitment start date

2012-10-01, 1391/07/10

Expected recruitment end date

2013-12-01, 1392/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of "Dosin" with triple therapy in eradication of helicobacter pylori infection in patients with helicobacter pylori infection and functional dyspepsia: A Randomized Controlled Clinical Trial.

Public title

Effects of "Dosin" in Helicobacter pylori infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 20-60 years old, documented helicobacter pylori infection and functional dyspepsia. Exclusion criteria: pregnancy, breast feeding, duodenal or gastric ulcer, cancer or bleeding, usage of NSAIDs, corticosteroids, bismuth, antibiotics, proton pump inhibitors and anticoagulants 4 weeks before the study.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization will be conducted by the table of random numbers.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Research Institute for Islamic and Complementary Medicine

Street address

No. 9, Pirnia Alley, Lalehzarno St., Jomhuri Ave., Tehran, IRAN

City

Tehran

Postal code**Approval date**

2012-03-06, 1390/12/16

Ethics committee reference number

1699/پ26/ م ط

Health conditions studied**1****Description of health condition studied**

Helicobacter pylori infection

ICD-10 code

B 98.0

ICD-10 code description

Helicobacter pylori [H.pylori] as the cause of diseases classified

Primary outcomes**1****Description**

Helicobacter pylori infection

Timepoint

Six weeks after beginning of intervention

Method of measurement

Urea Breath Test

Secondary outcomes**1****Description**

Dyspepsia

Timepoint

Six weeks after beginning of intervention

Method of measurement

Dyspepsia questionnaire

Intervention groups**1****Description**

Intervention: Mixture of

Category

Treatment - Drugs

2**Description**

Control group 1: Mixture of

Category

Treatment - Drugs

3**Description**

Control group 2: Amoxicillin capsule 1 g/bd, Clarithromycin capsule 500 mg/ bd and Pantoprazole tablet 20 mg/bd by mouth for 14 days. Amoxicillin of Farabi company and clarithromycin and pantoprazole of Tehran shimi company will be bought from Red Crescent pharmacy of Tehran.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoole Akram Hospital

Full name of responsible person

Mansureh Tavusi

Street address

Niayesh St., Sattarkhan Ave., Tehran, IRAN

City

Tehran

2

Recruitment center

Name of recruitment center

Added at 2012-12-31: Shahid Taleghani Hospital

Full name of responsible person

Added at 2012-12-31: Ramin Tavafzadeh, Babak Gholamin

Street address

Added at 2012-12-31: Shahid Taleghani Hospital, Shahid Beheshti Blv., Kermanshah, IRAN

City

Added at 2012-12-31: Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Institute for Islamic and Complementary Medicine, Tehran Unive

Full name of responsible person

Seid Ashrafeddin Gushegir

Street address

No. 9, Pirnia Alley, Lalehzarno St., Jomhuri Ave., Tehran, IRAN

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Institute for Islamic and Complementary Medicine, Tehran Unive

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

Research Institute for Islamic and Complementary Medicine, Tehran University of Medical Sciences

Full name of responsible person

Fataneh Hashem Dabaghian

Position

Faculty staff, Assistant professor

Other areas of specialty/work**Street address**

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Position

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Full name of responsible person

Maryam Taghavi Shirazi

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Researcher

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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