Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 for14 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 pomp 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/ ط م

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

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Person responsible for updating data

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Other areas of specialty/work

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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