Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative study of Nigella sativa and triple therapy in eradication of Helicobacter pylori in patients with non-ulcer dyspepsia

Protocol summary

Summary

Nigella sativa (N. sativa) seed is a commonly used herb which has been shown to possess in vitro antihelicobacter activity. The objective of the study is to evaluate the efficacy of N. sativa seeds in eradication of H. pylori infection in non-ulcer dyspeptic (NUD) patients. The study will be conducted on 110 adult patients, both sexes with the age range of 18-65 years, attending the Gastroenterology Division of the Department of Medicine, King Fahd Hospital of the University, AlKhobar, Saudi Arabia from March 2007 to August 2008. Patients complaining of dyspeptic symptoms and found positive for H. pylori infection as confirmed by histopathology and urease test will be included in the study. Those suffering from peptic ulcer, gastric cancer or other gastrointestinal bleeding as seen during endoscopy; or who have taking proton-pump inhibitors, bismuth or antibiotics in the last 4 weeks before endoscopy; or pregnant or lactating, or intolerant to therapeutic regimens will be excluded from the study. Approval from ethics committee and written consent from patients will be obtained. Patients will be randomly assigned to four groups, receiving: Triple therapy (clarithromycin, amoxicillin and omeprazole), 1g N. sativa and 40mg omeprazole, 2g N. sativa and 40mg omeprazole, or 3g N. sativa and 40mg omeprazole. Negative H. pylori stool antigen, 4 weeks after end of treatments will be considered as eradication. We hope that N.sativa will be a useful cheap and easily available alternate/adjunct treatment for the eradication of H.pylori.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138802061848N1**
Registration date: **2009-07-11, 1388/04/20**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2009-07-11, 1388/04/20

Registrant information

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Recruitment status

Recruitment complete

Funding source

King Faisal University, Dammam, Saudi Arabia

Expected recruitment start date

2007-03-15, 1385/12/24

Expected recruitment end date

2008-08-14, 1387/05/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of Nigella sativa and triple therapy in eradication of Helicobacter pylori in patients with non-ulcer dyspepsia

Public title

Study for effectiveness of Nigella sativa (Black seed) in patients with dyspepsia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) Patients complaining of dyspeptic symptoms 2) Patients with positive result for H. pylori infection confirmed by both histopathology and rapid urease test (CLO test) Exclusion criteria: 1) the endoscopy showed peptic ulcer, gastric cancer or other gastrointestinal bleeding 2) they had taken proton-pump inhibitors, bismuth or antibiotics in the last 4 weeks before endoscopy 3) pregnant or lactating 4) intolerant to therapeutic regimens

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee King Faisal University

Street address

King Faisal University

City

Dammam

Postal code

31451

Approval date

2009-06-13, 1388/03/23

Ethics committee reference number

KFU-LEC-129

Health conditions studied

1

Description of health condition studied

Non-ulcer dyspepsia

ICD-10 code

K30

ICD-10 code description

Dyspepsia

Primary outcomes

1

Description

Eradication of H. pylori

Timepoint

4 weeks after the end of treatment

Method of measurement

Negative stool antigen by rapid monoclonal immunochromatographic method (ImmunoCard STAT! HpSA, Meridian Bioscience Europe)

Secondary outcomes

1

Description

Improvment in dyspeptic symptoms (epigastric pain and reflux symptoms)

Timepoint

4 weeks after end of teatment

Method of measurement

Questionnaire

Intervention groups

1

Description

Triple therapy (clarithromycin+amoxicillin+omeprazole)

Category

Treatment - Drugs

2

Description

1g of Nigella sativa seeds powder in capsule + 40mg omeprazole

Category

Treatment - Drugs

3

Description

2g of Nigella sativa seeds powder in capsule + 40mg omeprazole

Category

Treatment - Drugs

4

Description

3g of Nigella sativa seeds powder in capsule + 40mg omeprazole

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
King Fahd Hospital of the University, Gastroenterology Division,
Full name of responsible person
Prof Abdelaziz Al-Quorain
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
KFU:8051
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
King Faisal University
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

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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