

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Name

Muhammad Akram Randhawa

###### Name of organization / entity

King Faisal University

###### Country

Saudi Arabia

###### Phone

00966-3-8577000/2146

###### Email address

mrandaau@kfu.edu.sa

##### 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**

Improvement in dyspeptic symptoms (epigastric pain and reflux symptoms)

#### **Timepoint**

4 weeks after end of treatment

#### **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

**Street address**

Gastroenterology Division, King Fahd Hospital of the  
University

**City**

Al-Khobar

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

King Faisal University

**Full name of responsible person**

Abdulaziz Abdulmohsin Almulhim

**Street address**

Dean Scientific Research and Higher Education, King  
Faisal University

**City**

Al-Ahsa

**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*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

King Faisal University

**Full name of responsible person**

Dr Muhammad Akram Randhawa

**Position**

MBBS, PhD, Associate Professor

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

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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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*