

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Comparing the effect of nigella sativa powder and cuminum cyminum powder in addition to conventional medical treatment of helicobacter pylori on eradication of bacteria , inflammatory and oxidative stress markers, dyspepsia and quality of life in patients with this infection

#### Protocol summary

##### Summary

The aim of this study is comparing the effect of nigella sativa powder and cuminum cyminum powder in addition to conventional medical treatment of helicobacter pylori on eradication of bacteria, inflammatory and oxidative stress markers, dyspepsia and quality of life in patients with this infection. This is the randomized controlled double blind trial. 90 men and women with the age of 18-65 with positive results of helicobacter pylori infection and dyspepsia symptoms enter the study. Exclusion criteria includes : having a history of gastric cancer and gastric surgery, active GI bleeding or intense gastritis, having chronic and inflammatory diseases such as diseases of kidney, liver, inflammatory bowel disease, heart ischemia, diabetes, cancer and..., taking any antibiotics or bismuth from 6 weeks before the start of the study, unwillingness to continue the study or getting out of reach. Individuals are randomly divided into 3 groups that receive nigella sativa powder or cuminum cyminum powder or pharmaceutical starch in capsules of 500 mg along with conventional drug therapy for helicobacter pylori infection for 8 weeks. The out comes of this study include checking the changes of IL8, hsCRP and MDA levels, dyspepsia symptoms, quality of life and eradication of bacteria by stool antigen test.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017091636204N1**  
Registration date: **2017-10-16, 1396/07/24**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-10-16, 1396/07/24

##### Registrant information

###### Name

Najmeh Hejazi

###### Name of organization / entity

Shiraz University of Medical Sciences, Faculty of Nutrition and Food Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3725 1005

###### Email address

nhejazi@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences (SUMS)

##### Expected recruitment start date

2017-10-02, 1396/07/10

##### Expected recruitment end date

2018-08-21, 1397/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of nigella sativa powder and cuminum cyminum powder in addition to conventional medical treatment of helicobacter pylori on eradication of bacteria , inflammatory and oxidative stress markers, dyspepsia and quality of life in patients with this

infection

### Public title

Comparing the effect of nigella sativa powder and cuminum cyminum powder on eradication of helicobacter pylori, dyspepsia and quality of life in patients with this infection

### Purpose

Treatment

### Inclusion/Exclusion criteria

Inclusion criteria: People who have any of the following conditions can participate in the study: 1. Having positive result of helicobacter pylori infection and dyspepsia symptoms 2. Having positive result of helicobacter pylori infection and dyspepsia symptoms with mild to moderate peptic ulcer 3. Having positive result of helicobacter pylori infection and dyspepsia symptoms with mild to moderate gastritis Exclusion criteria: 1. Having a history of gastric cancer or gastric surgery 2. Active GI bleeding and intense gastritis 3. Having an inflammatory or chronic disease (kidney disease, liver disease, inflammatory bowel disease, heart ischemia, diabetes, lung disease, asthma, cancer, HIV, systemic inflammation and...) 4. Taking any antibiotics or bismuth from 6 weeks before the study 5. Taking all types of medication for helicobacter pylori before the study 6. Pregnancy or lactation at the same time as studying 7. Drinking alcohol or using narcotic at the same time as studying 8. Eating a specific diet (vegetarian diet and ...) at the same time as studying 9. Body mass index greater than 30 10. Exiting patient during the study 11. Any changes in the use of anti-inflammatory drugs and corticosteroids at the same time as studying 12. Any changes in the use of supplements such as omega 3, selenium, zinc, beta carotene, vitamin E, C and... at the same time as studying 13. Unwillingness to continue the study

### Age

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

### Gender

Both

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **90**

### 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

Shiraz University of Medical Sciences

##### Street address

Shiraz University of Medical Sciences, Zand Blvd.

##### City

Shiraz

##### Postal code

##### Approval date

2017-07-19, 1396/04/28

##### Ethics committee reference number

IR.SUMS.REC.1396.74

## Health conditions studied

### 1

#### Description of health condition studied

Dyspepsia

#### ICD-10 code

K30

#### ICD-10 code description

Dyspepsia

### 2

#### Description of health condition studied

Helicobacter pylori infection

#### ICD-10 code

K31.9

#### ICD-10 code description

Disease of stomach and duodenum, unspecified

## Primary outcomes

### 1

#### Description

hsCRP

#### Timepoint

at the beginning and the end of the study ( after 8 weeks )

#### Method of measurement

hsCRP kit

## Secondary outcomes

### 1

#### Description

eradication percentage of helicobacter pylori

#### Timepoint

at the end of the study

#### Method of measurement

stool antigen test of helicobacter pylori

## 2

### **Description**

malondialdehyde

### **Timepoint**

at the beginning and the end of the study

### **Method of measurement**

malondialdehyde kit

## 3

### **Description**

interleukin 8

### **Timepoint**

at the beginning and the end of the study

### **Method of measurement**

interleukin 8 kit

## 4

### **Description**

quality of life

### **Timepoint**

at the beginning and the end of the study

### **Method of measurement**

sf-36 questionnaire

## 5

### **Description**

dyspepsia symptoms

### **Timepoint**

at the beginning and the end of the study

### **Method of measurement**

ROMEIII questionnaire

## **Intervention groups**

### 1

#### **Description**

control group : 4 capsules containing pharmaceutical starch daily for 8 weeks

#### **Category**

Placebo

### 2

#### **Description**

intervention group 1 : 4 capsules of 500 mg containing nigella sativa powder daily for 8 weeks

#### **Category**

Treatment - Other

### 3

#### **Description**

intervention group 2 : 4 capsules of 500 mg containing cuminum cyminum powder daily for 8 weeks

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Motahari clinic

##### **Full name of responsible person**

##### **Street address**

##### **City**

Shiraz

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Faghihi hospital

##### **Full name of responsible person**

##### **Street address**

##### **City**

Shiraz

### 3

#### **Recruitment center**

##### **Name of recruitment center**

Namazi hospital

##### **Full name of responsible person**

##### **Street address**

##### **City**

Shiraz

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shiraz University of Medical Sciences

##### **Full name of responsible person**

Dr. Seyed Basir Hashemi

##### **Street address**

Shiraz University of Medical Sciences, Zand Blvd.

##### **City**

Shiraz

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Shiraz University of Medical Sciences

#### **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**

Shiraz University of Medical Sciences, Faculty of  
Nutrition and Food Sciences

**Full name of responsible person**

Hedie Yousefnejad

**Position**

Master of Science in Nutrition

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

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences, Faculty of  
Nutrition and Food Sciences

**Full name of responsible person**

Najme Hejazi

**Position**

PHD in nutrition sciences, assistant professor of  
nutrition

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

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Fatholmobin alley, Razi blvd

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**Postal code****Phone**

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Nhejazi@sums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

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**Fax****Email**

h.ynejad@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