

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### The effect of adding nigella sativa powder in addition to conventional medical treatment of helicobacter pylori on plasma ghrelin and appetite in patients with this infection

#### Protocol summary

##### Study aim

The aim of this study is evaluating the effect of adding nigella sativa powder in addition to conventional medical treatment of helicobacter pylori on plasma ghrelin and appetite in patients with this infection.

##### Design

Double blind randomized parallel clinical trial with two groups of control and intervention with a sample size of 60

##### Settings and conduct

Helicobacter pylori positive patients are selected among those who have referred to Motahhari clinic based on inclusion and exclusion criteria. Then informed consent and other questionnaires for participants are completed. Ultimately, patients are randomly assigned to one of the intervention or control groups. Patients are not aware of the two groups being studied.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: positive result of helicobacter pylori infection  
Exclusion criteria : 1. Body mass index greater than 30  
2. Having an inflammatory or chronic diseases (kidney disease, liver disease, inflammatory bowel disease, heart ischemia, diabetes, lung disease, asthma, cancer, HIV, systemic inflammation and...)  
3. Having history of gastric cancer or gastric surgery  
4. Active GI bleeding and intense gastritis  
5. Taking any antibiotics or bismuth from 6 weeks before the study  
6. Taking all types of medication for helicobacter pylori before the study  
7. Pregnancy or lactation at the same time as studying  
8. Drinking alcohol or using narcotic at the same time as studying

##### Intervention groups

Control group : 4 capsules containing pharmaceutical starch daily for 8 weeks in addition to conventional medical treatment of helicobacter pylori  
Intervention group : 4 capsules of 500 mg containing nigella sativa powder daily for 8 weeks in addition to conventional

medical treatment of helicobacter pylori

##### Main outcome variables

Alteration ghrelin hormone and alteration appetite

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170916036204N7**

Registration date: **2018-08-08, 1397/05/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-08-08, 1397/05/17**

Update count: **0**

##### Registration date

2018-08-08, 1397/05/17

##### 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

2017-09-28, 1396/07/06

##### Expected recruitment end date

2018-08-22, 1397/05/31  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**

The effect of adding nigella sativa powder in addition to conventional medical treatment of helicobacter pylori on plasma ghrelin and appetite in patients with this infection

**Public title**

The effect of nigella sativa powder on appetite and appetite hormone in patients with helicobacter pylori

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

positive result of helicobacter pylori infection

**Exclusion criteria:**

Body mass index greater than 30 Having an inflammatory or chronic diseases (kidney disease, liver disease, inflammatory bowel disease, heart ischemia, diabetes, lung disease, asthma, cancer, HIV, systemic inflammation and...) Having history of gastric cancer or gastric surgery Active GI bleeding and intense gastritis Taking any antibiotics or bismuth from 6 weeks before the study Taking all types of medication for helicobacter pylori before the study Pregnancy or lactation at the same time as studying Drinking alcohol or using narcotic at the same time as studying

**Age**

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

**Gender**

Both

**Phase**

4

**Groups that have been masked**

- Participant
- Care provider
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization with fixed block size of two.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The capsules presented to the control group are filled with colored pharmaceutical starch, with the same appearance and packaging as those given to intervention group. So the patients do not recognize which of the two groups they are in. Also, the physician and the data analyst are unaware of this.

**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**

Iran, Fars, Shiraz, Shiraz University of Medical Sciences

**City**

Shiraz

**Province**

Fars

**Postal code**

71348-14336

**Approval date**

2017-08-30, 1396/06/08

**Ethics committee reference number**

Ir.Sums.Rec.1396.98

**Health conditions studied**

**1**

**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**

ghrelin hormone

**Timepoint**

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

**Method of measurement**

ghrelin kit

**Secondary outcomes**

**1**

**Description**

appetite

**Timepoint**

at the beginning and the end of the study

**Method of measurement**

appetite questionnaire

## Intervention groups

### 1

#### Description

control group : 4 capsules containing pharmaceutical starch daily for 8 weeks in addition to conventional medical treatment of helicobacter pylori

#### Category

Placebo

### 2

#### Description

intervention group : 4 capsules of 500 mg containing nigella sativa powder daily for 8 weeks in addition to conventional medical treatment of helicobacter pylori

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Motahari Clinic

##### Full name of responsible person

Mahvash Alizadeh

##### Street address

Motahari Clinic, Namazi square, Shiraz

##### City

Shiraz

##### Province

Fars

##### Postal code

7166776770

##### Phone

+98 71 3612 1000

##### Email

Nhejazi@sums.ac.ir

## 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-Vice Chancellor for Research Affairs Shiraz

##### City

Shiraz

##### Province

Fars

##### Postal code

7134814336

##### Phone

+98 71 3235 7282

#### Email

vcrdep@sums.ac.ir

#### 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

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## 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

##### Latest degree

Bachelor

##### Other areas of specialty/work

##### Street address

Department of Nutrition and Food Science, Fatholmobin alley, Razi blvd

##### City

Shiraz

##### Province

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##### Postal code

7153675541

##### Phone

+98 71 3725 1001

##### Fax

##### Email

H.YNEJAD@YAHOO.COM

##### Web page address

## 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

**Latest degree**

Ph.D.

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

Department of Nutrition and Food Science,  
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**Web page address****Person responsible for updating data****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

**Latest degree**

Bachelor

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

Department of Nutrition and Food Science,  
Fatholmobin alley, Razi blvd

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to  
make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to  
make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to  
make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to  
make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to  
make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to  
make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to  
make this available