Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 coms 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
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Iran (Islamic Republic of)
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+98 71 3725 1005
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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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Najme Hejazi

Position
PHD in nutrition sciences, assistant professor of nutrition

Other areas of specialty/work

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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