

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Evaluation of the effect of soft gel containing essential oil of *Satureja hortensis*(pyloricin) on eradicating and clinical symptoms of *Helicobacter pylori* infection

Protocol summary

Study aim

Evaluation of the effect of soft gel containing essential oil of *Satureja hortensis*(pyloricin) on eradicating and clinical symptoms of *Helicobacter pylori* infection

Design

Randomized clinical trial, controlled with placebo, parallel, double blind, single center

Settings and conduct

This clinical trial is performed on 60 individuals with *Helicobacter pylori* infection which referred to Kashan Shahid Beheshti Hospital. Individuals based on table of random numbers will be divided to routine treatment+pyloricin or placebo soft capsule, BID for 2 weeks. All drugs are presented in the same package and the physician and patients are blind. After analyzing data, codes will be decoded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Confirmation of *Helicobacter Pylori* infection: Patients with functional dyspepsia or gastroduodenal ulcer have indications of eradication of *Helicobacter pylori* infection. Exclusion criteria: A person with advanced chronic disease: Any allergy to the drugs used in the study: Pregnancy or breastfeeding: Smoking and alcohol: Having a history of treatment to eradicate *Helicobacter pylori* infection: Taking antibiotics or bismuth 4 weeks before entering the study: Constipation

Intervention groups

Intervention group: Routine treatment(Omeprazole20(Produced in Abidi Pharmaceutical Company) +Amoxicillin1+ Clarithromycin500(Produced in Toliddaru Pharmaceutical Company) BID)+Herbal soft capsule contain essential oil of *Satureja hortensis*(Produced in Barij essence Pharmaceutical Company) ,BID for 2 weeks orally. Control group:Routine treatment(Omeprazole20(Produced in Abidi Pharmaceutical Company) +Amoxicillin1+ Clarithromycin500(Produced in Toliddaru Pharmaceutical

Company) BID)+ placebo soft capsule(Produced in Barij essence Pharmaceutical Company), BID for 2 weeks orally.

Main outcome variables

Clinical signs: eradication rate of *Helicobacter pylori*

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130211012438N27**

Registration date: **2018-09-19, 1397/06/28**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-19, 1397/06/28**

Update count: **0**

Registration date

2018-09-19, 1397/06/28

Registrant information

Name

Mohsen Taghizadeh

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1555 0021

Email address

taghizadeh_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of soft gel containing essential oil of Satureja hortensis(pyloricin) on eradicating and clinical symptoms of Helicobacter pylori infection

Public title
Evaluation of the effect of pyloricin soft gel on Helicobacter pylori infection

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of Helicobacter Pylori infection by gastroenterologist with the help of a sample of pathology taken in the endoscopy or a positive result of anti-Helicobacter pylori antibodies in the serum sample of patients Patients with functional dyspepsia or gastroduodenal ulcer have indications of eradication of Helicobacter pylori infection
Exclusion criteria:
A person with advanced chronic disease Any allergy to the drugs used in the study Pregnancy or breastfeeding Substance abuse or alcohol use Having a history of treatment to eradicate Helicobacter pylori infection Taking antibiotics or bismuth 4 weeks before entering the study Constipation

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomized based on table of random numbers

Blinding (investigator's opinion)
Double blinded

Blinding description
Coding and similar packaging. The physician, patient, researcher and statistical analyzer are blind. At the end of the study and analysis of data, codes are decoded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kashan University of Medical Sciences
Street address
Kashan University of Medical Sciences, Kashan
City
Kashan
Province
Isfahan
Postal code
۸۷۱۵۹۸۸۱۴۱
Approval date
2018-05-21, 1397/02/31
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1397.008

Health conditions studied

1

Description of health condition studied
Helicobacter pylori infection
ICD-10 code
B96.81
ICD-10 code description
Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

Primary outcomes

1

Description
Clinical signs
Timepoint
Before intervention, 2 weeks after the initial intervention
Method of measurement
questionnaire

2

Description
eradication rate of helicobacter pylori
Timepoint
after 1 months from the end of treatment
Method of measurement
stool antigen for helicobacter pylori

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Rutin treatment(Omeprazole20(Produced in Abidi Pharmaceutical Company) +Amoxicillin1+ Clarithromycin500(Produced in Toliddaru Pharmaceutical Company) BID)+ Herbal soft capsule contain essential oil of Satureja hortensis(Produced in Barij essence Pharmaceutical Company) ,BID for 2 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Rutin treatment(Omeprazole20(Produced in Abidi Pharmaceutical Company) +Amoxicillin1+ Clarithromycin500(Produced in Toliddaru Pharmaceutical Company) BID)+placebo soft capsule (Produced in Barij essence Pharmaceutical Company), BID for 2 weeks orally.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

dr Mohhamad Reza Molaghanbari

Street address

Shahid Beheshti Hospital, Kashan

City

Kashan

Province

Isfahan

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Phone

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Email

mollaghanbari-m@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Barij Research Center of Medicinal Herbs

Full name of responsible person

Miss Laleh Hejazi

Street address

Kashan Mashhad Ardehal Road, KM44

City

Kashan

Province

Isfahan

Postal code

1178

Phone

+98 86 4854 0000

Email

info@barijessence.com

Web page address

http://www.barijessence.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Barij Research Center of Medicinal Herbs

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

2

Sponsor

Name of organization / entity

Vice chancellor for research of Kashan University of Medical Sciences

Full name of responsible person

Dr Gholam Ali Hamidi

Street address

Kashan university of Medical Sciences, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

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Email

hamiidi@yahoo.com

Web page address

http://kaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Kashan University of
Medical Sciences
Proportion provided by this source
50
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
Kashan University of Medical Sciences
Full name of responsible person
M.Taghizadeh
Position
phd
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Mohsen Taghizadeh
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Associate Professor
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Other areas of specialty/work
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Phone
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+98 31 5557 1112
Email
taghizadeh_m@kaums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Barij research center of medicinal herbs
Full name of responsible person
M.Mahlouji
Position
Expert in clinical research
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
KM 44 Kashan-Mashhad Ardehal
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Province
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Postal code
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Fax
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mahnaz.mahlouji@yahoo.com
Web page address

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