Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Helicobacterpylori infection which referred to Kashan Shahid Beheshti Hospital.Individuals based on table of random numbers will be divided to routin treatment+ pyloricin or placebo soft capsule,BID for 2 weeks. All drug 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: Routin 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:Routin 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)
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+98 36 1555 0021
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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
Isfehan

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:Routin 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: Routin 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
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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
Isfehan
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
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Postal code
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Phone
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hamiidi@yahoo.com
Web page address
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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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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Mohsen Taghizadeh

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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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
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Isfehan

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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