Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

The Study of Combinatory effect of Cydonia oblanga, Cinnamomum zeylanicom, Pistacia lentiscus and Honey in Eradication of Gastric Helicobacter pylori Infection in patients with dyspepsia

Protocol summary

Study aim

The Study of Combinatory effect of fruits of Quince, cinnamon and mastic and Honey in Eradication of Gastric Helicobacter pylori Infection in patients with dyspepsia

Design

Clinical trial of phase 2-3 with control and intervention groups, with parallel groups, double blind, randomized

Settings and conduct

This study will be performed as a randomized clinical trial on patients over 18 years of age with H. pylori positive referred to the gastrointestinal clinic of Golestan Hospital in Ahvaz. Patients will receive routine daily treatment. These patients will be randomly divided into two groups who will randomly receive a bottle containing placebo or herbal syrup. Unique codes provided by the software will be used on medicine boxes. Symptoms of dyspepsia will be assessed based on a questionnaire before and after the intervention. This questionnaire has 12 questions. These items are scored between 0 and 5 by the subjects

Participants/Inclusion and exclusion criteria

Inclusion criteria: People with one or more symptoms of dyspepsia (based on the Reflux Disease Questionnaire), patients over 18 years of age with a positive H. pylori test, women with a negative pregnancy test. Exclusion criteria: having a chronic disease that leads to long-term use of various drugs, previous history of gastrointestinal ulcers or gastrointestinal bleeding, gastric cancer

Intervention groups

Patients are randomly assigned to treatment and control groups. The test and control groups will receive 30 ml of herbal syrup or placebo twice a day for 2 weeks.

Main outcome variables

Burning sensation in the back of the chest, feeling of pain in the back of the chest, Heartburn, feeling of upper abdominal pain, feeling of acid taste, feeling of movement of the material upwards of the stomach, belching, contusion, cough, difficulty swallowing, bitter taste

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200128046288N3**
Registration date: **2020-07-24, 1399/05/03**
Registration timing: **prospective**

Last update: **2020-07-24, 1399/05/03**
Update count: **0**

Registration date

2020-07-24, 1399/05/03

Registrant information

Name

Fereshteh Golfakhrabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8378

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-19, 1399/06/29

Expected recruitment end date

2020-12-19, 1399/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Study of Combinatory effect of Cydonia oblanga, Cinnamomum zeylanicom, Pistacia lentiscus and Honey in Eradication of Gastric Helicobacter pylori Infection in patients with dyspepsia

Public title
The Study of Combinatory effect of Cydonia oblanga, Cinnamomum zeylanicom, Pistacia lentiscus and Honey in Eradication of Gastric Helicobacter pylori Infection

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People who have one or more symptoms of dyspepsia (based on the Reflux Disease Questionnaire (RDQ)) Patients over 18 years with H.pylori positive test The women in the study had a negative pregnancy test

Exclusion criteria:
Having a chronic illness that leads to long-term use of a variety of medications. (Cardiovascular diseases, liver failure, kidney failure) Previous history of gastrointestinal ulcers or gastrointestinal bleeding Gasteric cancer Allergy to plants especially fruits of Quince, Cinnamon and mastic

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The block randomization method is used Blocking is used to balance the number of samples assigned to each study group, because we have two intervention groups, use equal 4 blocks and create all 4 possible modes and then with Excel software we randomly select a number of blocks. The label of interventions to one of the letters A or B and the sequence of randomization determined by the statistical consultant. For allocation concealment, drug delivery and the sequence of randomization is not available to researchers and evaluators while is the responsibility of the off-site individual.

Blinding (investigator's opinion)
Double blinded

Blinding description
Unique codes, which is generated by the software, will be used on the drug and placebo boxes. By entering each individual into the study based on the produced sequence, the drug or placebo box in which the code is registered, will be assigned to the individual. During the research, the randomization list is held by the statistic consultant, and the participants, the project implementer and all those who participate in the measurement of the indicators will not be aware of the assigned groups

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی جندی شاپور اهواز

Street address
Ahvaz Jundishapur University of Medical Sciences,, Golestan street

City
Ahvaz

Province
Khouzestan

Postal code
61357-15794

Approval date
2020-07-03, 1399/04/13

Ethics committee reference number
IR.AJUMS.REC.1399.343

Health conditions studied

1

Description of health condition studied
Helicobacter pylori and dyspepsia

ICD-10 code
B96.81

ICD-10 code description
Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

Primary outcomes

1

Description
Burning sensation in the back of the chest

Timepoint
Before and 2 week after the intervention

Method of measurement
Reflux Disease Questionnaire

2

Description
Feeling of pain in the back of the chest
Timepoint
Before and 2 week after the intervention
Method of measurement
Reflux Disease Questionnaire

3

Description
Heartburn
Timepoint
Before and 2 week after the intervention
Method of measurement
Reflux Disease Questionnaire

4

Description
Feeling of upper abdominal pain
Timepoint
Before and 2 week after the intervention
Method of measurement
Reflux Disease Questionnaire

5

Description
Acid taste
Timepoint
Before and 2 week after the intervention
Method of measurement
Reflux Disease Questionnaire

6

Description
Feeling the material move towards the top of the stomach
Timepoint
Before and 2 week after the intervention
Method of measurement
Reflux Disease Questionnaire

7

Description
Beiching
Timepoint
Before and 2 week after the intervention
Method of measurement
Reflux Disease Questionnaire

8

Description
Contusion
Timepoint
Before and 2 week after the intervention
Method of measurement
Reflux Disease Questionnaire

9

Description
Cough
Timepoint
Before and 2 week after the intervention
Method of measurement
Reflux Disease Questionnaire

10

Description
Swallowing disorder
Timepoint
Before and 2 week after the intervention
Method of measurement
Reflux Disease Questionnaire

11

Description
Bitter taste sensation
Timepoint
Before and 2 week after the intervention
Method of measurement
Reflux Disease Questionnaire

12

Description
Feeling of movement of material in the stomach upwards (throat or mouth)
Timepoint
Before and 2 week after the intervention
Method of measurement
Reflux Disease Questionnaire

Secondary outcomes

1

Description
The rate of drug side effects
Timepoint
During drug use
Method of measurement
Patient Report

Intervention groups

1

Description
Intervention group: In addition to receiving routine treatment, 30 ml of herbal syrup will be taken twice a day for 2 weeks. The herbal syrup includes fruit of Quince, cinnamon, mastic and honey which will be made by the researchers of the project and based on the formula of Iranian traditional medicine resources.
Category
Treatment - Drugs

2

Description
Control group: In addition to receiving routine treatment, 30 ml of placebo syrup will be taken twice a day for 2 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastroenterology Clinic of Golestan hospital in Ahvaz
Full name of responsible person
Dr Saeed Seyedian
Street address
Gastroenterology Clinic of Golestan hospital, Golestan street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Badavi
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Ahvaz Jundishapur University of Medical Sciences, Golestan street
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Email
Badavim@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Fereshteh golfakhrabadi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Ph.D.
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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Title and more details about the data/document

Only part of the data will be shared

When the data will become available and for how long

The access time is up to 6 months after the results are published

To whom data/document is available

Six months after the publication of articles from this study, the data obtained will be made available to the applicant researchers for further analysis

Under which criteria data/document could be used

Six months after the publication of articles from this study, the data obtained will be made available to the applicant researchers for further analysis.

From where data/document is obtainable

Applicants can email the responsible author to receive the requested data golfakhrabadi@yahoo.com

What processes are involved for a request to access data/document

Applicants will have access to the data from the present study by emailing the responsible author for up to one month.golfakhrabadi@yahoo.com

Comments