

# 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

golfakhrabadi-f@ajums.ac.ir

##### 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 oblonga, 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 oblonga, 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**

Khuzestan

**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

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135733184

**Phone**

+98 61 3374 3001

**Email**

golfakhrabadi@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Badavi

**Street address**

Ahvaz Jundishapur University of Medical Sciences, Golestan street

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135733184

**Phone**

+98 61 3336 2414

**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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**City**

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**Province**

Khouzestan

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6135733184

**Phone**

+98 61 3373 8378

**Email**

golfakhrabadi@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Fereshteh golfakhrabadi

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6135733184

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**Email**

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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