

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Evaluation of therapeutic effect of Iranian natural honey on H. pylori infection

#### Protocol summary

##### Study aim

The effect of treatment regimen containing natural Iranian honey on the eradication of Helicobacter pylori infection

##### Design

Clinical trial with parallel control group, non-blind, randomized, phase 3 on 200 patients. A sealed envelope was used for randomization.

##### Settings and conduct

In this study, all patients referred to the gastrointestinal clinic of Shahid Beheshti Hospital in Kashan according to the endoscopy and biopsy results, peptic ulcer or gastritis as well as Helicobacter pylori infection were included in the study. Four weeks after the end of treatment, eradication of the infection will be checked by a stool antigen test for Helicobacter Pylori. Also from patients about the rate of adherence to the treatment regimen will be questioned.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: refer to the gastrointestinal clinic of Shahid Beheshti Hospital in Kashan; endoscopic and biopsy-confirmed peptic ulcer or gastritis; infection with Helicobacter Pylori confirmed by biopsy and fecal antigen test. Exclusion criteria: previous history of treatment for Helicobacter Pylori; history for diabetes mellitus; existence of gastrointestinal anomalies.

##### Intervention groups

After controlling the entry and exit criteria of patients by selecting sealed envelopes, the study population are divided into case and control groups. Both groups are under treatment with the standard four-drug regimen of omeprazole, clarithromycin, bismuth and amoxicillin for two weeks. The case group in addition to receiving the standard drug regimen will receive every 8 hours 21 grams of natural honey Iran, produced by Mehram Company.

##### Main outcome variables

Helicobacter pylori infection eradication

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151106024901N4**

Registration date: **2021-03-24, 1400/01/04**

Registration timing: **retrospective**

Last update: **2021-03-24, 1400/01/04**

Update count: **0**

##### Registration date

2021-03-24, 1400/01/04

##### Registrant information

##### Name

Seyyed Mehdi Rasoolimanesh

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5554 0021

##### Email address

m\_rasulimanesh@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-02-08, 1399/11/20

##### Expected recruitment end date

2021-03-21, 1400/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Evaluation of therapeutic effect of Iranian natural honey on H. pylori infection

**Public title**

Evaluation of therapeutic effect of Iranian natural honey on H. pylori infection

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Refer to the gastrointestinal clinic of Shahid Beheshti Hospital in Kashan Endoscopic and biopsy-confirmed peptic ulcer or gastritis Infection with Helicobacter Pylori infection confirmed by biopsy and fecal antigen test

**Exclusion criteria:**

Reluctance to participate in the project Previous history of treatment for Helicobacter pylori Having diabetes mellitus Existence of gastrointestinal anomalies

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

No information

**Sample size**

Target sample size: **200**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization method and description of each method: simple randomization; randomization unit: individual; randomization tool: sealed envelope.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Kashan University of Medical Sciences

**Street address**

Hekmat 56, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

81151-87159

**Approval date**

2011-11-30, 1390/09/09

**Ethics committee reference number**

IR.TBZMED.REC.1399.786

**Health conditions studied****1****Description of health condition studied**

Gastric or duodenal ulcers

**ICD-10 code**

K25

**ICD-10 code description**

Gastric ulcer

**Primary outcomes****1****Description**

Helicobacter pylori eradication

**Timepoint**

Before treatment, 4 weeks after the end of treatment

**Method of measurement**

Stool antigen test

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: omeprazole capsules 20 mg daily, clarithromycin 500 mg tablets every 12 hours, bismuth tablets 2 tablets daily and amoxicillin capsules 1 gram every 12 hours and Iranian natural honey made by Mehram company for 2 weeks daily 2 tablespoons

**Category**

Treatment - Drugs

**2****Description**

Intervention group: omeprazole capsules 20 mg daily, clarithromycin 500 mg tablets every 12 hours, bismuth tablets 2 tablets daily and amoxicillin capsules 1 g every 12 hours

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center**

Name of recruitment center

Gastroenterology Clinic, Shahid Beheshti Hospital,  
Qutb Ravandi Blvd.

**Full name of responsible person**

Seyed Mahdi Rrasuli Manesh

**Street address**

56 Hekmat Street

**City**

Kashan

**Province**

Isfahan

**Postal code**

81151-87159

**Phone**

+98 31 5554 0021

**Email**

m\_rasulimanesh@kaums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Hamidreza Banafshe

**Street address**

Shahid Beheshti Hospital Complex, Qutb Ravandi Blvd

**City**

Kashan

**Province**

Isfahan

**Postal code**

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**Phone**

+98 31 5554 0021

**Email**

banafshe57@hotmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kashan 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**

Kashan University of Medical Sciences

**Full name of responsible person**

Seyed Mahdi Rasuli Manesh

**Position**

Assistant Professor of Gastroenterology

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Gastroenterology Clinic of Kashan Shahid Beheshti Hospital, Qutb Ravandi Blvd.

**City**

Kashan

**Province**

Isfahan

**Postal code**

81151-87159

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## Person responsible for scientific inquiries

**Contact**

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Kashan University of Medical Sciences

**Full name of responsible person**

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Assistant Professor of Gastroenterology

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**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**

Not applicable

**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