Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Isfehan

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

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Kashan

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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

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+98 31 5554 0021

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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

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

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Person responsible for updating data

Contact

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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