

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effect of the three-drug regimen of H. Pylori eradication with and without probiotics on the eradication treatment: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of the three-drug regimen of H. Pylori eradication with and without probiotics on the eradication treatment

Design

This is a double-blind randomized clinical trial, phase II, in which 150 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with H. Pylori infection referring to the Shahid Beheshti Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years, H. pylori infection, Exclusion criteria: Pregnancy or breastfeeding, Gastric cancer, Kidney or liver failure, History of gastric surgery, Previous history of Helicobacter pylori treatment

Intervention groups

Intervention group: Amoxicillin capsule 1000 mg (manufactured by Dana Pharmaceuticals Co.) every 12 hours for 12 weeks, and Clarithromycin tablet 500 mg (manufactured by Dana Pharmaceuticals Co.) every 12 hours for 12 weeks, and omeprazole capsule 20 mg (manufactured by Dana Pharmaceuticals Co.) every 12 hours For 12 weeks, and Probiotics Balance Probiotics capsule (British Made) every 12 hours for 2 weeks
Control group: Amoxicillin capsule 1000 mg (manufactured by Dana Pharmaceuticals Co.) every 12 hours for 12 weeks, and Clarithromycin tablet 500 mg (manufactured by Dana Pharmaceuticals Co.) every 12 hours for 12 weeks, and omeprazole capsule 20 mg (manufactured by Dana Pharmaceuticals Co.) every 12 hours For 12 weeks

Main outcome variables

Primary outcome: H. Pylori eradication Secondary

outcome: Assessing gastrointestinal complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N344**

Registration date: **2020-03-09, 1398/12/19**

Registration timing: **retrospective**

Last update: **2020-03-09, 1398/12/19**

Update count: **0**

Registration date

2020-03-09, 1398/12/19

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of the three-drug regimen of H. Pylori eradication with and without probiotics on the eradication treatment: a double-blind randomized clinical trial

Public title

Effect of the three-drug regimen of H. Pylori eradication with and without probiotics on the eradication treatment

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 65 years, H. pylori infection,

Exclusion criteria:

Pregnancy or breastfeeding, Gastric cancer, Kidney or liver failure, History of gastric surgery, Previous history of Helicobacter pylori treatment,

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drugs will be given in coded envelopes. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-09-01, 1397/06/10

Ethics committee reference number

IR.UMSHA.REC.1397.402

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

H. 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**

H. Pylori eradication

Timepoint

12 weeks after the intervention

Method of measurement

By respiratory urease test

Secondary outcomes**1****Description**

Assessing gastrointestinal complications

Timepoint

12 weeks after the intervention

Method of measurement

By taking history

Intervention groups

1

Description

Intervention group: Amoxicillin capsule 1000 mg (manufactured by Dana Pharmaceuticals Co.) every 12 hours for 12 weeks, and Clarithromycin tablet 500 mg (manufactured by Dana Pharmaceuticals Co.) every 12 hours for 12 weeks, and omeprazole capsule 20 mg (manufactured by Dana Pharmaceuticals Co.) every 12 hours For 12 weeks, and Probiotics Balance Probiotics capsule (British Made) every 12 hours for 2 weeks

Category

Treatment - Drugs

2

Description

Control group: Amoxicillin capsule 1000 mg (manufactured by Dana Pharmaceuticals Co.) every 12 hours for 12 weeks, and Clarithromycin tablet 500 mg (manufactured by Dana Pharmaceuticals Co.) every 12 hours for 12 weeks, and omeprazole capsule 20 mg (manufactured by Dana Pharmaceuticals Co.) every 12 hours For 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital in Hamadan city

Full name of responsible person

Zahra Rahkoy

Street address

Shahid Beheshti Hospital, Eram Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0283

Email

zahra.rahkoy@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid

Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Zahra Rahkoy

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

zahra.rahkoy@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Alireza kHalilian

Position

Internist

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

khalilian@umsha.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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