

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of effectiveness of four drugs: furazolidone, amoxicillin, bismuth, pantoprazole: with and without probiotic supplementation on eradication of helicobacter pylori in patients with dyspepsia

Protocol summary

Study aim

Determining a better approach for treatment of patients with dyspepsia

Design

The double blind randomized placebo-controlled clinical trial with independent groups, phase III, on 100 patients (50 in each group). For randomization, computer program will be used.

Settings and conduct

All patients will be visited by the physician, who recruits the patients into the study according to the inclusion and exclusion criteria. Based on the computer codes. The patients will be categorized into two groups and will receive the drugs in sealed packets without name.

Participants/Inclusion and exclusion criteria

Patients older than 18 years old, who referred with chronic dyspepsia to GI clinic of Loghman Hakim hospital, candidate of upper endoscopy without history of Helicobacter treatment, using antibiotics in the past four weeks, severe heart failure, renal failure, pulmonary failure, and renal failure were included

Intervention groups

Group A patients with dyspepsia receiving 4 drugs of furazolidone, amoxicillin, bismuth, and pantoprazole with probiotic Group B patients with dyspepsia receiving 4 drugs of furazolidone, amoxicillin, bismuth, and pantoprazole without probiotic

Main outcome variables

Response to treatment, adherence to treatment, and complications of drug regimens in the two groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200518047494N1**

Registration date: **2020-06-12, 1399/03/23**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-12, 1399/03/23**

Update count: **0**

Registration date

2020-06-12, 1399/03/23

Registrant information

Name

Nafeh Noorbakhsh sabet

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4423 8325

Email address

nafeh.noorbakhsh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-06, 1398/09/15

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of four drugs: furazolidone, amoxicillin, bismuth, pantoprazole: with and without probiotic supplementation on eradication of helicobacter pylori in patients with dyspepsia

Public title

effectiveness of probiotic supplementation on eradication of helicobacter pylori

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients older than 18 years, who referred for chronic dyspepsia to GI clinic of Loghman Hakim hospital, candidate for upper endoscopy

Exclusion criteria:

Patients with a history of eradication of Helicobacter pylori patients taking antibiotics during the past four weeks Patients with a history of severe heart failure Patients with a history of severe liver failure Patients with a history of severe pulmonary failure Patients with a history of severe renal failure

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly assignment of patients to one of two treatment groups: Group A, 14-day regimen with high-dose furazolidone and probiotic supplement Group B, 14-day regimen with high-dose furazolidone with placebo Randomization will be performed by computer program and the computer codes were specified to each patient, referred to pharmacy for getting drug or placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

Groups were determined by the code generated by computer program for each person and the patient is referred to the pharmacy with this code to receive drug or placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medicine College- Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Shahid-Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-02-19, 1397/11/30

Ethics committee reference number

IR.SBMU.MSP.REC.1397.682

Health conditions studied

1

Description of health condition studied

dyspepsia

ICD-10 code

K30

ICD-10 code description

Functional dyspepsia

Primary outcomes

1

Description

response to treatment

Timepoint

Two weeks after the initiation of treatment

Method of measurement

Fecal antigen test

Secondary outcomes

1

Description

Adherence to treatment

Timepoint

Two weeks after initiation of treatment

Method of measurement

By counting the number of pills

2

Description

Adverse effects of the drugs

Timepoint

Two weeks after initiation of treatment

Method of measurement

Asking the patient

Intervention groups

1

Description

Intervention group: Treated with probiotic supplement in addition to 4-drug regimen

Category

Treatment - Drugs

2

Description

Control group: Treated with 4-drug regimen without probiotic supplement

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman-Hakim Hospital

Full name of responsible person

Dr. Shahriyar Pournik

Street address

Loghman-Hakim Hospital, Special st., Lashkar ave., South Kargar St.

City

Tehran

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1333625445

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+98 21 5541 9005

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loghman.hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Shahriyar Pournik

Street address

Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Yemen St., Shahid Chamran Highway

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info@sbmu.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Medical college- Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nafeh Noorbakhsh Sabet

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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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

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

Yes - There is 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

We intend to publish the results of the study as a scientific article in valid journals.

When the data will become available and for how long

About a year

To whom data/document is available

It depends on the journal's policies

Under which criteria data/document could be used

It depends on the journal's policies

From where data/document is obtainable

the journal's website

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

It depends on the journal's policies

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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Nafeh Noorbakhsh Sabet

Position

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Latest degree

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