

# 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

##### Province

Tehran

##### Postal code

1333625445

##### Phone

+98 21 5541 9005

##### Email

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 23871

##### Email

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

##### Street address

No.18, East Rezaie, Nahid st., Marzdaran St.

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##### Province

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##### Phone

+98 21 4423 8325

##### Fax

##### Email

nafeh.noorbakhsh@gmail.com

## Person responsible for scientific inquiries

#### Contact

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Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Nafeh Noorbakhsh Sabet

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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

**Full name of responsible person**

Nafeh Noorbakhsh Sabet

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