

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of efficacy and safety of quadruple regimens containing furazolidone in patients with Helicobacter pylori infection

Protocol summary

Study aim

Safety and efficacy of four-drug regimens containing furazolidone in H. pylori eradication

Design

Clinical trial work in the form of an intervention in which 135 patients who were randomly divided into three groups of 45 and treated with coded drug packages were divided into parallel and double-blind randomized phase 2 groups. Method: Simple randomization. Randomization unit: Individual. Randomization tool. Using the site <http://www.randomizer.Org>

Settings and conduct

Adult patients referred to the endoscopy room clinic of Luqman Hakim Hospital with confirmed positive h. pylori infection are randomly divided into three therapeutic intervention groups that include regimens of 4 drugs containing furazolidone. The intervention groups are double-blind, and the drug packages are coded as Each intervention group is delivered and the effectiveness and safety of these regimens in eradication are examined

Participants/Inclusion and exclusion criteria

Entry conditions: H. pylori infection proven by standard diagnostic methods and age over seventeen years
Conditions of non-entry: drug sensitivity to the studied diet, pregnancy, chronic diseases (kidney, liver, lung), patients treated with other antibiotics and probiotics, etc.

Intervention groups

It contains three experimental groups that are under the regimen of four drugs containing furazolidone First intervention group: furazolidone, proton pump inhibitor, bismuth, amoxicillin Second intervention group: furazolidone, proton pump inhibitor, bismuth, tetracycline The third intervention group: furazolidone, proton pump inhibitor, bismuth, levofloxacin

Main outcome variables

Drug side effects, eradication rate of H.pylori

General information

Reason for update

Acronym

no

IRCT registration information

IRCT registration number: **IRCT20230202057305N1**

Registration date: **2023-03-03, 1401/12/12**

Registration timing: **prospective**

Last update: **2023-03-03, 1401/12/12**

Update count: **0**

Registration date

2023-03-03, 1401/12/12

Registrant information

Name

seide maryam moghadam ziabary

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6690 6234

Email address

maryam.moghadam201@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-03, 1402/01/14

Expected recruitment end date

2023-06-04, 1402/03/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and safety of quadruple regimens containing furazolidone in patients with Helicobacter pylori infection

Public title

Investigating the effect of furazolidone drug for the treatment of stomach bacterial infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of H. pylori infection in patients by standard diagnostic methods Over seventeen years of age

Exclusion criteria:

History of known drug sensitivity to the studied drug regimen pregnancy Having chronic diseases (pulmonary, kidney, liver) Unwillingness to participate in the study Patients treated with other treatment methods such as probiotics, other antibiotics, etc.

Age

From 17 years old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: 135

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: simple. Randomization unit: individual. Randomization tool: randomization using the site <http://www.randomizer.Org>, which is extracted using random numbers obtained by the software, patients are divided into one of 3 groups: Amoxicillin A, Tetracycline T, and Levofloxacin L. In other words, We extract random numbers based on the number of samples introduced on the site

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients were randomly selected and placed in groups that were unaware of the other groups, and the medication package was delivered to them in coded form.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti Medical School

Street address

Masal - Shahid Tabatabai St. - Stovar Alley - No. 5

City

Masal

Province

Guilan

Postal code

4381965747

Approval date

2023-02-22, 1401/12/03

Ethics committee reference number

IR.SBMU.MSP.REC.1401.589

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

Eradication and safety of drug regimens containing furazolidone in patients with H. pylori infection

Timepoint

Investigating the eradication rate of H. pylori two weeks after the end of the treatment regimen

Method of measurement

Standard diagnostic methods include RUT, histology staining, bacterial culture, antigen test

Secondary outcomes

1

Description

H. pylori eradication, drug safety

Timepoint

Two weeks after the end of the eradication treatment

Method of measurement

Urea breath test, fecal antigen, bacterial culture, histology

Intervention groups

1

Description

Intervention group: First intervention group: furazolidone, proton pump inhibitor, bismuth, amoxicillin. . which is in the form of furazolidone 100 every 12 hours, pentazol 40 every 12 hours, bismuth 240 every 12 hours, and amoxicillin 1000 every 12 hours and from Obeid Pharmaceutical Company for 10-14 days.

Category

Treatment - Drugs

2

Description

Intervention group: second intervention group: furazolidone, proton pump inhibitor, bismuth, tetracycline. Furazolidone 100 every 12 hours, pentazol 40 every 12 hours, bismuth 240 every 12 hours, tetracycline 500 every 6 hours. From Obeid Pharmaceutical Company for 10-14 days

Category

Treatment - Drugs

3

Description

Intervention group: The third intervention group: furazolidone, proton pump inhibitor, bismuth, levofloxacin in the form of furazolidone 100 every 12 hours, pentazol 40 every 12 hours, bismuth 240 every 12 hours, and levofloxacin 500 daily from Obeid Pharmaceutical Company for 10-14 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman-e Hakim Hospital

Full name of responsible person

Seyedeh Maryam Moghadam Ziyabari

Street address

Tehteran Province, Tehran South Kargar St

City

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Fax

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Email

Lcrdc@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti Faculty of Medicine, Shahid Arabi St., Student Blvd., Valenjak, Tehran

City

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1985717443

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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

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

Seyed Maryam Moghadam Ziabari

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Tabatabai St. - Stovar Alley - No. 5

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Seyed Maryam Moghadam Ziabari

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data can be shared after de-identification

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

public

Under which criteria data/document could be used

Scientific and therapeutic research

From where data/document is obtainable

Send your request to

maryam.moghadam201@gmail.com

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

Just submit your request in email

maryam.moghadam201@gmail.com

Comments