

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Comparison of low dose and high dose of furazolidone in the treatment of *Helicobacter pylori* infection

#### Protocol summary

##### Study aim

Comparison of two regimens containing low dose and a high dose of Furazolidone in the treatment of *Helicobacter pylori*

##### Design

This study is a randomized clinical trial (Randomized Clinical Trial) study. Which was conducted in 2016-17 13 and includes patients with peptic ulcer referring to Shahid Sayyad Shirazi Hospital in Gorgan. In this clinical trial study, the study samples were randomly selected from patients with peptic ulcer referring to Shahid Sayyid Shirazi Hospital in Gorgan, which are confirmed by endoscopic examination of the upper digestive system and rapid urease test in *Helicobacter pylori* infection. Will be selected.

##### Settings and conduct

This study is a randomized clinical trial (Randomized Clinical Trial) study. Which was conducted in 2016-17 13 and includes patients with peptic ulcer referring to Shahid Sayyad Shirazi Hospital in Gorgan.

##### Participants/Inclusion and exclusion criteria

Criteria for entering the study include peptic ulcer with endoscopic diagnosis and proof of *Helicobacter pylori* infection with RUT test and consent to cooperation. Outcome criteria include pregnancy, cancer and liver and kidney failure, diabetes mellitus, history of NSAIDs, PPI, bismuth and antibiotics over the past 4 weeks, history of smoking and alcohol, and history of drug sensitivity.

##### Intervention groups

Group A: Low-dose OfAB treatment containing: Amoxicillin mg-BD 1000, Furazolidone mg-BD 100, Omeprazole mg-BD20, and Bismuth sub-citrate mg-BD 240 for 2 weeks B-Group II: High-dose OFAB treatment including: Amoxicillin mg-BD 1000, Furazolidone mg-BD 200, Umperazole mg-BD20 and Bismuth subitrate mg-BD 240 for 2 weeks

##### Main outcome variables

Reduce side effects; discontinue treatment

#### General information

##### Reason for update

##### Acronym

ندارد

##### IRCT registration information

IRCT registration number: **IRCT20160118026097N6**

Registration date: **2021-05-11, 1400/02/21**

Registration timing: **retrospective**

Last update: **2021-05-11, 1400/02/21**

Update count: **0**

##### Registration date

2021-05-11, 1400/02/21

##### Registrant information

##### Name

Jamshid Vafaemanesh

##### Name of organization / entity

Qom University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 252931933

##### Email address

j.vafaemanesh@muq.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2015-07-23, 1394/05/01

##### Expected recruitment end date

2016-07-22, 1395/05/01

##### Actual recruitment start date

2016-07-22, 1395/05/01

##### Actual recruitment end date

2018-01-21, 1396/11/01

##### Trial completion date

2018-06-22, 1397/04/01

## Scientific title

Comparison of low dose and high dose of furazolidone in the treatment of Helicobacter pylori infection

## Public title

Comparison of low dose and high dose of furazolidone in the treatment of Helicobacter pylori infection

## Purpose

Health service research

## Inclusion/Exclusion criteria

### Inclusion criteria:

Peptic ulcer diagnosis with endoscopic diagnosis test  
Helicobacter pylori infection with RUT consent to cooperate

### Exclusion criteria:

Pregnancy Cancer or Liver Failure Diabetes Mellitus  
History of Cigarette History of Alcohol History of Drug Sensitivity

## Age

From **18 years** old to **100 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **170**

Actual sample size reached: **170**

## Randomization (investigator's opinion)

Randomized

## Randomization description

This study will be performed by a random sampling method, block allocation. In such a way that In this study, 60 patients with corona will be randomly divided into two groups. The selection of groups will be based on the fact that individuals will be assigned to groups based on block randomization. Block size 4 is considered. So we have six blocks of four, ABAB, ABBA, AABB, BAAB BBAA, BABA. The selection of each block will also be random and will be done using dice. For example, if the number 5 comes in the dice roll, the AABB block is considered and Therefore, the first two patients are assigned to treatment A, and the two patients are then assigned to treatment B. The dice will be thrown ten times to complete the allocation of patients to treatment groups. Treatment with dexamethasone and control will also be based on accident (coin toss).

## 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

Golestan University of Medical Sciences

##### Street address

Golestan Research Center of Gastroenterology and Hepatology-GRCGH (GOUMS), Golestan University of Medical Sciences, Gorgan, Iran

##### City

gorgan

##### Province

Golestan

##### Postal code

01732430319

#### Approval date

2015-06-22, 1394/04/01

#### Ethics committee reference number

IR.GOUMS.REC.1394.135

## Health conditions studied

### 1

#### Description of health condition studied

Helicobacterpylori Eradication

#### ICD-10 code

K25

#### ICD-10 code description

Gastric ulcer

## Primary outcomes

### 1

#### Description

Response to treatment-Helicobacter pylori eradication after drug treatment with urease respiratory test

#### Timepoint

Six weeks after drug treatment

#### Method of measurement

Urease Respiratory Test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: After obtaining informed consent and full explanation of the treatment process to the patient and his companions regarding the treatment process, under low-dose four-drug treatment (OfAB) including amoxicillin mg-BD 1000, furazolidone mg-BD 100, omeprazole mg-BD20, and bismuth 240 mg-BD subcitrate for 2 weeks.

#### Category

Treatment - Drugs

2

### Description

Intervention group 2: After obtaining informed consent and full explanation of the treatment process to the patient and his companions about the treatment process, under treatment with four high-dose drugs (OFAB) including: amoxicillin mg-BD 1000, furazolidone mg-BD 200, omeprazole mg-BD20 and bismuth sub-citrate 240 mg-BD for 2 weeks.

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Shahid Sayyad Shirazi Educational Therapy in Gorgan

#### Full name of responsible person

vafaemanesh jamshid

#### Street address

Shahid Sayyad Shirazi Educational Therapy in Gorgan

#### City

gorgan

#### Province

Golestan

#### Postal code

4934174515

#### Phone

+98 25 3612 2526

#### Email

jvafaemanesh@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Gorgan University of Medical Sciences

#### Full name of responsible person

hosein momeni

#### Street address

Gorgan - At the beginning of Sixta Kola Road, a complex of philosophical higher education

#### City

gorgan

#### Province

Golestan

#### Postal code

79142-49361

#### Phone

+98 17 3230 3988

#### Email

h.momeni@gu.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor

### organization/entity?

Yes

### Title of funding source

Gorgan 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

Ghorm University of Medical Sciences

#### Full name of responsible person

jamshid vafaemanesh

#### Position

asAssociate Professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Internal Medicine

#### Street address

Qom - Shahid Lavasani Street (Coastal) - Qom University of Medical Sciences

#### City

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#### Province

Ghorm

#### Postal code

3713649373

#### Phone

+98 25 3612 2526

#### Email

jvafaemanesh@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Ghorm University of Medical Sciences

#### Full name of responsible person

jamshid vafaemanesh

#### Position

Associate Professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Internal Medicine

#### Street address

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

Ghous University of Medical Sciences

**Full name of responsible person**

jamshid vafaemanesh

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Qom - Shahid Lavasani Street (Coastal) - Qom

University of Medical Sciences

**City**

qom

**Province**

Ghous

**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