

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Compare the results of eradication of *Helicobacter pylori* in two different doses of furazolidone quadruple therapy in the treatment of patients with peptic ulcer

#### Protocol summary

##### Summary

Objective: To evaluate the treatment of *Helicobacter pylori* eradication in peptic ulcer disease. Two different treatment regimens with high dose furazolidone will be used to determine the effectiveness of any of these regimens and treatment regimen should be recommended. Methods: In this clinical trial, 170 patients with peptic ulcer admitted to the hospital martyr Sayyad Shirazi, an upper gastrointestinal endoscopy study with *H. pylori* infection were selected. None of the subjects in the study population history of smoking, alcohol and had previous treatment of *Helicobacter pylori*. In this study, 85 samples divided into two groups and treated with different doses of furazolidone were two drug regimens 4. Six weeks after completion of treatment of all samples analyzed in order to prove *Helicobacter Pylori* Eradication carbon-labeled urea breath test was performed. The patients in terms of response to treatment will be evaluated and the eradication of *Helicobacter pylori*.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016011826084N1**

Registration date: **2016-08-10, 1395/05/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-08-10, 1395/05/20

##### Registrant information

##### Name

Majid Rajabi

##### Name of organization / entity

Golestan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3254 6240

##### Email address

m.rajabi@goums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Golestan Research Center of Gastroenterology and Hepatology

##### Expected recruitment start date

2015-03-21, 1394/01/01

##### Expected recruitment end date

2016-03-19, 1394/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Compare the results of eradication of *Helicobacter pylori* in two different doses of furazolidone quadruple therapy in the treatment of patients with peptic ulcer

##### Public title

The effect of two different regimens furazolidone on *Helicobacter pylori*

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: peptic ulcer with endoscopic diagnosis, proof of *Helicobacter pylori* infection by testing RUT; consenting to the partnership. Exclusion criteria: pregnancy, the risk of cancer, liver failure and kidney

disease, diabetes mellitus, history of taking NSAIDs; PPI; bismuth; anti- antibiotics during the past 4 weeks, history of smoking and alcohol; history of drug allergy.

#### **Age**

No age limit

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **170**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethic Committee Golestan University of Medical Sciences

##### **Street address**

Sayyad Shirazi Hospital, Sayyad Shirazi Blvd, Gorgan, Golestan, Iran

##### **City**

Gorgan

##### **Postal code**

#### **Approval date**

2010-08-20, 1389/05/29

#### **Ethics committee reference number**

IR.GOUMS.REC.1394.135

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Peptic Ulcer

#### **ICD-10 code**

K27

#### **ICD-10 code description**

Gastroduodenal Ulcer NOS

## **Primary outcomes**

### 1

#### **Description**

H.Pylori eradication

#### **Timepoint**

After Intervention

#### **Method of measurement**

ELISA Method

## **Secondary outcomes**

### 1

#### **Description**

Peptic Ulcer cure

#### **Timepoint**

after intervention

#### **Method of measurement**

by Endoscopy

## **Intervention groups**

### 1

#### **Description**

Group I: Quadruple Therapy (OfAB) with low-dose (amoxicillin mg-BD 1000, furazolidone mg-BD 100, omeprazole mg-BD20 Vbysmvt subcitrate mg-BD 240 for 2 weeks)

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Group II: Quadruple therapy (OFAB) high dose (amoxicillin mg-BD 1000, furazolidone mg-BD 200, omeprazole mg-BD20 Vbysmvt subcitrate mg-BD 240 for 2 weeks)

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Sayyad Shirazi Hospital

##### **Full name of responsible person**

Dr Majid Rajabi

##### **Street address**

Sayyad Shirazi Hospital, Sayyad Shirazi Blvd, Gorgan, Golestan, Iran

##### **City**

Gorgan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Golestan University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Hossein Taziki

**Street address**

Sayyad Shirazi Hospital, Sayyad Shirazi Blvd, Gorgan,  
Golestan, Iran

**City**

Gorgan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Golestan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Golestan University of Medical Sciences

**Full name of responsible person**

Dr Majid Rajabi

**Position**

Resident of Internal Medicine

**Other areas of specialty/work**

**Street address**

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majid\_rk5863@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Position**

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**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*