

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Comparison of Quadruple and Triple Furazolidone Containing Regimens on Eradication of Helicobacter Pylori ,in Patients with Helicobacter pylori Infected Duodenal Ulcer , Gastric Ulcer and/or Erosive Gastrodeudinitis .

#### Protocol summary

##### Summary

The aim of this study is to evaluate safety and efficacy of ten days quadruple and triple furazolidone- based regimen in eradication of Helicobacter pylori. 372 H-pylori infected patients with proven peptic ulcer , duodenal and /or gastric erosions by endoscopy will be randomized into three groups: group A(OABF) with furazolidone (F) (200 mg bid);groupB( OABM-F); metronidazole (M) (500 mg bid) for the first5 days, followed by furazolidone (F) (200 mg Bid) for the second 5 days; group C(OAF) with furazolidone (F) (200 mg Tid).Duration of all eradication regimens will be ten days.Two months after treatment, a C14-urea breath test will be performed.Analysis of eradication rates will be done by intention-to-treat and per-protocol methods.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013120715701N1**  
Registration date: **2013-12-31, 1392/10/10**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-12-31, 1392/10/10

##### Registrant information

##### Name

Marjan Mokhtare

##### Name of organization / entity

Mazandaran university of medical sciences,Imam Khomeini Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 15 1226 1700

##### Email address

m.mokhtare@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mazandaran University of Medical Sciences

##### Expected recruitment start date

2012-06-01, 1391/03/12

##### Expected recruitment end date

2013-01-30, 1391/11/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Quadruple and Triple Furazolidone Containing Regimens on Eradication of Helicobacter Pylori ,in Patients with Helicobacter pylori Infected Duodenal Ulcer , Gastric Ulcer and/or Erosive Gastrodeudinitis .

##### Public title

Furazolidone Containing Regimens in Eradication of Helicobacter Pylori

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria : Helicobacter pylori infected duodenal ulcer; gastric ulcer;Gastric Erosion ;Deudenal Erosion;Age >18 year old. Exclusion criteria :pregnancy ;lactation ; history of previous H.pylori eradication ; taking antibiotics and/or bismuth and/or non-steroidal anti inflammatory drugs during the previous four weeks;

concomitant use of anticoagulant or corticosteroid; consuming substantial amounts of alcohol; history of gastric surgery; significant underlying disease such as; liver; renal; pulmonary; cardiac disease and neoplasms ; G6PD deficiency ; history of drug allergy to any medication in this study .

#### **Age**

From **18 years** old to **83 years** old

#### **Gender**

Both

#### **Phase**

3

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

*No information*

#### **Sample size**

Target sample size: **372**

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

Randomized

#### **Randomization description**

#### **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**

Mazandaran University of Medical Sciences and Health Services

##### **Street address**

Joybar 3 WAY ,Imam Sq,

##### **City**

Sari

##### **Postal code**

#### **Approval date**

2012-11-07, 1391/08/17

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

91-139

## **Health conditions studied**

### 1

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

Peptic Ulcer Disease(H.Pylori Eradication)

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

K25,K26, K

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

Gastric ulcer, Duodenal ulcer, Gastritis,unspecified ,Duodenitis

## **Primary outcomes**

### 1

#### **Description**

Helicobacter.pylori eradication rate

#### **Timepoint**

2 months after the completion of treatment courser

#### **Method of measurement**

Urea Breath Test

## **Secondary outcomes**

### 1

#### **Description**

Adverse effect of Drugs

#### **Timepoint**

Daily recording during and after the treatment course

#### **Method of measurement**

Medical history and record sheet

## **Intervention groups**

### 1

#### **Description**

Intervention group:triple therapy including ,omperazol 20 mg Bid,amoxycillin 1 gr Bid and furazolidone 200 mg Tid , all of them for 10 days

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group 1:quadrapl therapy including, omperazol 20 mg Bid,amoxycillin 1gr Bid,bismuth 240 mg Bid and furazolidone 200 mg Bid ,all of them for 10 days

#### **Category**

Treatment - Drugs

### 3

#### **Description**

Intervention group 2:quadrapl sequential therapy including; omperazol 20 mg Bid,amoxycillin 1 gr Bid and bismuth 240 mg Bid ,all of them for 10 days.Metronidazol 500 mg Bid for first 5 days and then furazolidone 200 mg Bid for second 5 days.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Imam Khomeini Hospital

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

Dr .Marjan Mokhtare

**Street address**

Razi Street

**City**

Sari

**2**

**Recruitment center**

**Name of recruitment center**

Tooba Clinic

**Full name of responsible person**

Dr.Vahid Hoseini ,Gastroenterologist

**Street address**

**City**

Sari

**3**

**Recruitment center**

**Name of recruitment center**

Gastroenterologists office or clinic

**Full name of responsible person**

Dr.Marjan Mokhtare

**Street address**

**City**

Sari

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for Research, Mazandaran university of medical sciences

**Full name of responsible person**

Dr.Ahmadali Enayati

**Street address**

Moallem Square, Assistance of researches and technology

**City**

Sari

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for Research, Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Marjan Mokhtare

**Position**

MD,Gastroenterologist

**Other areas of specialty/work**

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Inflammatory Diseases of Upper Gastrointestinal Tract Research Center

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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*