

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The comparison between effects and side effects of seven days or ten days quadruple therapy regimens (Bismuth sub citrate, Levofloxacin, Amoxicillin and Pantazole) in eradication of H.pylori infection.

#### Protocol summary

##### Summary

This study is a clinical trial which aims to compare the efficacy and adverse effects of seven and ten-day quadruple regimen in the treatment of patients with H. pylori referred to the gastroenterology and liver Clinic in Rasht. H. Pylori infection is confirmed according to carbon-13 or 14-UBT, pathology or stool antigen. Demographic data, smoking and commodities recorded for all patients. Then patients are randomly divided into two groups. The first group is treated with four drugs (bismuth sub citrate, levofloxacin, amoxicillin, pantozol) for seven days. The second group received the same formula for a period of ten days. Complications are recorded for both groups 2 weeks after treatment. Eight weeks after the treatment, Urea Breath Test (with carbon 14) is done for patients to determine resistance or eradication of infection.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201406141155N19**

Registration date: **2015-07-10, 1394/04/19**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-07-10, 1394/04/19

##### Registrant information

###### Name

Farahnaz Joukar

###### Name of organization / entity

Guilan University of Medical Sciences,  
Gastrointestinal and liver disease Research Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 1553 5116

##### Email address

info@gldrc.org

##### Recruitment status

**Recruitment complete**

##### Funding source

Gastrointestinal and Liver Diseases Research Center,  
Guilan University of Medical Sciences

##### Expected recruitment start date

2015-07-15, 1394/04/24

##### Expected recruitment end date

2015-11-22, 1394/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparison between effects and side effects of seven days or ten days quadruple therapy regimens (Bismuth sub citrate, Levofloxacin, Amoxicillin and Pantazole) in eradication of H.pylori infection.

##### Public title

Compare seven and ten days quadruple regimen for H. pylori

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: H. pylori infection has been confirmed in accordance with Urea Breath Test with carbon-13 or 14 or pathology or stool antigen, The patient satisfaction  
Exclusion criteria: Pregnant and lactating women,

Patients with esophageal cancer, Liver cirrhosis, Heart failure; kidney failure, History of seizures, Hematologic diseases; Allergy to drugs, Patients with an incomplete course of treatment; Severe complications; Discontent to treatment

#### Age

From **18 years** old to **80 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **220**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee Guilan University of Medical Sciences .

##### Street address

Namjoo Ave

##### City

Rasht

##### Postal code

#### Approval date

2014-07-14, 1393/04/23

#### Ethics committee reference number

1930175713

## Health conditions studied

### 1

#### Description of health condition studied

Helicobacter pylori infection

#### ICD-10 code

B98.0

#### ICD-10 code description

Helicobacter pylori [H. pylori] as the cause of diseases classified to other chapters

## Primary outcomes

### 1

#### Description

Eradication of infection

#### Timepoint

Eight weeks after completion of treatment

#### Method of measurement

Urea breath test (Carbon 14)

## Secondary outcomes

### 1

#### Description

Complications

#### Timepoint

Two weeks after completion of treatment

#### Method of measurement

According to the case history

## Intervention groups

### 1

#### Description

Administration of quadruple therapy for seven days as follows: Bismuth sub citrate (Chemidarou company) 240 mg BID, Levofloxacin (Abidi company) 500 mg daily, Amoxicillin (Chemidarou company) 1 g BID, Pantozol (Nokomed company) 20 mg BID

#### Category

Treatment - Drugs

### 2

#### Description

Administration of quadruple therapy for ten days as follows: Bismuth sub citrate (Chemidarou company) 240 mg BID, Levofloxacin (Abidi company) 500 mg daily, Amoxicillin (Chemidarou company) 1 g BID, Pantozol (Nokomed company) 20 mg BID

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Gastrointestinal and Liver Diseases Research Center, Guilan

##### Full name of responsible person

Dr. Mansour Ghanaei Fariborz

##### Street address

Gastrointestinal and Liver Diseases Research Center, Razi hospital, Sardar jangle Ave

##### City

Rasht

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vince Chancellor for Research Guilan University of Medical Sciences .

**Full name of responsible person**

Dr. Tabari Khomeirani Rasool

**Street address**

Sadati St, Namjoo Ave

**City**

Rasht

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vince Chancellor for Research Guilan 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**

Guilan Gastrointestinal and Liver Diseases Research Center

**Full name of responsible person**

Joukar Farahnaz

**Position**

Assistant in Guilan Gastrointestinal and Liver Diseases Research Center

**Other areas of specialty/work****Street address**

Gastrointestinal and Liver Diseases Research Center, Razi hospital, Sardar jangle Ave

**City**

Rasht

**Postal code**

955655-41448

**Phone**

+98 13 3353 5116

**Fax****Email**

info @glsrc.org

**Web page address**

www.glsrc.org

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Guilan Gastrointestinal and Liver Diseases Research Center

**Full name of responsible person**

Dr. Mansour Ghanaei Fariborz

**Position**

professor

**Other areas of specialty/work****Street address**

Gastrointestinal and Liver Diseases Research Center, Razi hospital, Sardar jangle Ave

**City**

Rasht

**Postal code****Phone**

+98 13 3353 5116

**Fax****Email**

info @glsrc.org

**Web page address**

www.glsrc.org

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Guilan Gastrointestinal and Liver Diseases Research Center

**Full name of responsible person**

Dr. Masihypour Behnam

**Position**

Internal Medicine Resident

**Other areas of specialty/work****Street address**

Razi hospital, Sardar jangle Ave

**City**

Rasht

**Postal code**

955655-41448

**Phone**

+98 13 3353 5116

**Fax****Email**

Dr.bmasihypour@yahoo.com

**Web page address**

www.glsrc.org

## 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*