

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of two anti helicobacterpylori second-line regiments in patients with peptic ulcer disease after failure of first line triple drug regiment

#### Protocol summary

##### Summary

The aim of this study is to compare two second-line therapy for H. pylori eradication regimen in patients with peptic ulcer disease after failure of first-line triple therapy Sayyad Shirazi Hospital in Gorgan. Patients with peptic ulcers caused by Helicobacter pylori infection and resistance to first-line the three-drug regimen will be enrolled. Patients randomly will be assigned to one of two treatment groups: 1) OLA 2) OFAB. 6 weeks after the end of treatment, UBT breathe test will be done and eradication rates in the two groups will be compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015123025770N1**  
Registration date: **2016-07-07, 1395/04/17**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-07-07, 1395/04/17

##### Registrant information

##### Name

Laleh Abbasi

##### Name of organization / entity

Golestan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3254 6627

##### Email address

dr.laleh.abbasi@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Gastroenterology Research Center of Golestan province

##### Expected recruitment start date

2014-03-21, 1393/01/01

##### Expected recruitment end date

2015-09-21, 1394/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of two anti helicobacterpylori second-line regiments in patients with peptic ulcer disease after failure of first line triple drug regiment

##### Public title

Comparing second-line treatment regimens for H. pylori

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: All patients with peptic ulcer confirmed by endoscopy; Perfect for first-line treatment; Resistance and non-response to first-line therapy for Helicobacter pylori eradication  
Exclusion criteria: lack of regular use of antibiotics because of severe side effects.

##### Age

No age limit

##### Gender

Both

##### Phase

2

##### Groups that have been masked

*No information*

## Sample size

Target sample size: 120

## 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 Blv, Gorgan, Golestan, Iran

##### City

Gorgan

##### Postal code

#### Approval date

2010-09-23, 1389/07/01

#### Ethics committee reference number

IR.GOUMS.REC.1394.40

## 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

Percent

## Secondary outcomes

### 1

#### Description

Peptic Ulcer cure

#### Timepoint

after intervention

#### Method of measurement

Percent

## Intervention groups

### 1

#### Description

in OLA group : patients will be treated with : omeprazole 40 mg daily, levofloxacin 500 mg and amoxicillin 2 g for 2 weeks

#### Category

Treatment - Drugs

### 2

#### Description

in OFAB group patients will be treated with: omeprazole 40 mg, 480 mg bismuth subcitrate, furazolidone 400 mg and amoxicillin 2 g for 2 weeks

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sayyad Shirazi Hospital

##### Full name of responsible person

Dr Laleh Abbasi

##### Street address

Sayyad Shirazi Hospital, Sayyad Shirazi Blv, 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 Taziki

##### Street address

Sayyad Shirazi Hospital, Sayyad Shirazi Blv, 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 Laleh Abbasi

**Position**

Resident of Internal Medicine

**Other areas of specialty/work**

**Street address**

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laleh.abbasi3@gmail.com

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Golestan University of Medical Sciences

**Full name of responsible person**

Dr Mohammadreza Seyedmajidi

**Position**

Subspecialty of Gastrology

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Golestan University of Medical Sciences

**Full name of responsible person**

Dr Laleh Abbasi

**Position**

Resident of Internal Medicine

**Other areas of specialty/work**

**Street address**

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**Fax**

**Email**

**Web page address**

**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*