

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

Sayyad Shirazi Hospital, Sayyad Shirazi Blv, Gorgan,
Golestan, Iran

City

Gorgan

Postal code

Phone

+98 17 3242 1660

Fax

Email

laleh.abbasi3@gmail.com

Web page address

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

Street address

Sayyad Shirazi Hospital, Sayyad Shirazi Blv, Gorgan,
Golestan, Iran

City

Gorgan

Postal code

Phone

+1 32229561

Fax

Email

mrsmajidi55@yahoo.com

Web page address

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

Sayyad Shirazi Hospital, Sayyad Shirazi Blv, Gorgan,
Golestan, Iran

City

Gorgan

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Phone

+98 17 3242 1660

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