

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Sequential therapy versus the best quadruple drug therapy for helicobacter pylori eradication

Protocol summary

Summary

The aim of this study is to evaluate Sequential therapy versus the best quadruple drug therapy for helicobacter pylori eradication. 296 patients with duodenal ulcer in whom H.pylori infection has been documented by rapid urease test will be enrolled in the study. The patients will be randomly received one of following interventions: 1) Pantoprazole 40mg (BD) + Amoxicillin 1g (BD) + Bismuth 240mg (BD) for 2 weeks and Furazolidone 200mg (BD) just during the first week 2) Pantoprazole 40mg (BD) for 10 days + Amoxicillin 1g (BD) just during the first 5 days + Clarithromycin 500mg (BD) and Tinidazole 500mg (BD) just during the second 5 days. Patients will be visited after the treatment course to be asked about their compliance to treatment and side effects. H pylori eradication will be tested at least 8 weeks after the treatment course using C14-UBT.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138807022499N1**

Registration date: **2010-02-06, 1388/11/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-02-06, 1388/11/17

Registrant information

Name

Hafez Tirgar Fakheri

Name of organization / entity

Mazandaran University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 15 1226 1700

Email address

hfakheri@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research - Mazandaran University of Medical Sciences

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2010-09-23, 1389/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Sequential therapy versus the best quadruple drug therapy for helicobacter pylori eradication

Public title

Sequential therapy versus the best quadruple drug therapy for helicobacter pylori eradication

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age more than 18 years Exclusion criteria: Previous history of receiving any H.p eradication regimen, Taking H2 blocker, proton pump inhibitor, Bismuth or Antibiotics during the 2 weeks prior to the study, Taking anticoagulants, ketoconazole or corticosteroids, History of gastric or esophageal surgery, Severe cardiovascular, pulmonary or endocrine disease, Renal failure, Hepatic diseases, Malignancies, Alcoholism, G6PD deficiency, Pregnancy or breast feeding

Age
From **18 years** old to **90 years** old
Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **296**

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

Mazandaran University of Medical Sciences

Street address

Sari

City

Sari

Postal code

Approval date

2008-11-20, 1387/08/30

Ethics committee reference number

87-82

Health conditions studied

1

Description of health condition studied

Peptic Ulcer Disease (H. Pylori eradication)

ICD-10 code

K26

ICD-10 code description

Duodenal ulcer

Primary outcomes

1

Description

Helicobacter pylori eradication

Timepoint

2 months after the completion of treatment course

Method of measurement

urease breathing test

Secondary outcomes

1

Description

Side effects of drugs

Timepoint

daily recording during and after the treatment course

Method of measurement

classifying as mild, moderate or severe side effects

Intervention groups

1

Description

Intervention group: Pantoprazole 40mg (BD) for 10 days + Amoxicillin 1g (BD) just during the first 5 days + Clarithromycin 500mg (BD) and Tinidazole 500mg (BD) just during the second 5 days

Category

Treatment - Drugs

2

Description

Control group: Pantoprazole 40mg (BD) + Amoxicillin 1g (BD) + Bismuth 240mg (BD) for 2 weeks and Furazolidone 200mg (BD) just during the first week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Hafez Fakheri

Street address

Imam Khomeini Hospital, Sari, Razi street

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. Seyed Jalal Hosseinimehr

Street address

Vice Chancellor For Research, Mazandaran University
of Medical Sciences, Sari

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

Dr Hafez Tirgar Fakheri

Position

Associate Professor

Other areas of specialty/work

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Email

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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