Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Sequential therapy versus the best quadriple 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

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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 quadriple drug therapy for helicobacter pylori eradication

Public title

Sequential therapy versus the best quadriple 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 breating test

Secondary outcomes

1

Description
Side effects of drugs
Timepoint
daily recording during and after the treatmen 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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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