Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

hybrid therapy in H.pylori

Protocol summary

Summary

The aim of this study is to evaluate Sequential therapy versus hybrid therapy for helicobacter pylori eradication.Inclusion criteria: age more than 18 years and less than 80 years with duodenal or gastric ulcers; duodenal or gastric erosions and helicobacter pylori positivity. Exclusion criteria: Previous history of receiving any H.pylori 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, Pregnancy or breast feeding. 296 patients with PUD(peptic ulcer disease) in whom H.pylori infection has been documented by rapid urease test or pathology will be enrolled in the study. The patients will be randomly received one of following interventions: 1) Hybrid: [pantoprazole 40mg (BD) + Amoxicillin 1g (BD)] x2weeks + Clarithromycin 500mg (BD) and Tinidazole 500mg (BD) during secon dweek. 2) Sequential : Pantoprazole 40mg (BD) for 10 days + Amoxicillin 1g (BD) just during the first 5 days + Clarithromycin 500mg (BD) and Tinidazole 500mg (BD) both just during the second 5 days in control group. Patients will be visited after the treatment course to be asked about their compliance to treatment and side effects. H pylori eradication that is primary end poin will be tested at least 8 weeks after the treatment course using C14-UBT (14-carbon urea breath test).

General information

Acronym

sequential-concomitant (hybrid)

IRCT registration information

IRCT registration number: **IRCT201110312499N2**
Registration date: **2011-12-02, 1390/09/11**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2011-12-02, 1390/09/11

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

2011-03-21, 1390/01/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

hybrid therapy in H.pylori

Public title

comparison of sequential-concomitant hybrid to sequential therapy in h.pylori eradication rate

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: age more than 18 years and less than 80 years with duodenal or gastric ulcers; duodenal or gastric erosions and helicobacter pylori positivity. Exclusion criteria: Previous history of receiving any H.pylori 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, Pregnancy or breast feeding
Age
From **18 years** old to **80 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
Imam Khomeini Hospital, Sari, Razi street Sari Mazandaran
City
sari
Postal code
Approval date
2011-08-07, 1390/05/16
Ethics committee reference number
90-107

Health conditions studied

1

Description of health condition studied
PUD(H.PYLORI ERADICATION REGIMEN)
ICD-10 code
K25.9,K26.
ICD-10 code description
GASTRIC ULCER,DUODENAL ULCER,PEPTIC ULCER DISEASE, GASRTRODUODENITIS

Primary outcomes

1

Description
Helicobacter pylori eradication rate
Timepoint
2 months after the completion of treatment course
Method of measurement
urease breath 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) + Amoxicillin 1g (BD) + Clarithromycin 500mg (BD) and Tinidazole 500mg (BD) during the first 2 weeks
Category
Treatment - Drugs

2

Description
Control 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

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr Hafez Fakheri
Street address
Imam Khomeini Teaching Hospital, Sari, Razi street

Sari Mazandaran 33131-48166 00981512261700

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.Ahmadali Enayati

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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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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