

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Efficacy of Two Hybrid regimens (10 days and 14 days) for Eradication of Helicobacter Pylori Infection

Protocol summary

Summary

Main objectives: - Determine the eradication rate in hybrid regimens 10 and 14 days - Comparison of two regimens eradication rate. Hypotheses : - The effectiveness of the hybrid 10-days regimen in eradicating HP is close to 14 days. - Patient compliance is better and side-effect is less in 10 days than 14 days regimen. In this randomized clinical trial in 250 patients with Duodenal Ulcer or Gastric Ulcer and or Erosive Gastritis and Duodenitis that diagnosed by gastric endoscopy in Toba Clinic and Sari Emam Khomeni Hospital enrolled in this study. Patients were randomly divided into two groups: 125 individuals will receive regimen A and 125 individuals will receive regimen B. Diagnosis of Helicobacter Pylori Infection are based on gastric pathology, Rapid Urease Test (RUT) . The patients have 18 years or greater without following finding enrolled in this study. - Pregnancy and Lactation . - Previously regimens for helicobacter pylori eradication. - Proton pump inhibitor or antibiotics consumption in last two weeks - History of Gastric Surgery 12 weeks after therapy, Helicobacter Pylori Infection evaluated by Urea Breath Test (UBT) or endoscopy and biopsy Regimen A: (hybrid 10 -day: Pantoprazole 40 /BID and Amoxicillin 1 g BID for 10 days and Clarithromycin 500 mg + Tinidazole 500 mg BID for second 5 days) Regimen B : (Hybrid 14 -day : Pantoprazole 40 / BID and Amoxicillin 1 g BID for 14 days and Clarithromycin 500 mg + Tinidazole 500 mg BID for second 7 days)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112415510N1**

Registration date: **2014-02-02, 1392/11/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-02-02, 1392/11/13

Registrant information

Name

Seyed Mohammad Valizadeh Toosi

Name of organization / entity

Mazandaran University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mazandaran University Of Medical Sciences

Expected recruitment start date

2013-12-31, 1392/10/10

Expected recruitment end date

2014-04-30, 1393/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Efficacy of Two Hybrid regimens (10 days and 14 days) for Eradication of Helicobacter Pylori Infection

Public title

Comparison of Efficacy of Two Hybrid Regimens (10 days and 14 days)for Eradication of Helicobacter pylori Infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with endoscopic findings of gastric or duodenal ulcer or gastric and duodenal erosion ; Helicobacter pylori infection ; patients older than 18 year and less than 80 years. Exclusion criteria : pregnancy and lactation ; previously received Helicobacter pylori therapy ; patients received PPI (proton pump inhibitor) or H2 RA (histamine 2 receptor antagonist) in last 2 weeks or within 4 weeks who received antibiotics ; history of surgery on the stomach ; Patients with confirmed advanced disease , severe cardiac, pulmonary , endocrine , chronic renal failure, chronic liver disease or have cancer ; The consumption of alcoholic beverages

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: **250**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Assistant, Mazandaran University Of Medical sciences

Street address

Moallem Square

City

Sari

Postal code

324776119

Approval date

2013-12-04, 1392/09/13

Ethics committee reference number

92-130

Health conditions studied

1

Description of health condition studied

gastric ulcer

ICD-10 code

k25

ICD-10 code description

gastric ulcer

Primary outcomes

1

Description

Helicobacter Pylori Infection.

Timepoint

Before the intervention, and 12 weeks after intervention

Method of measurement

Before intervention, endoscopy and biopsy and RUT(Rapid urease Test), and after intervention endoscopy and biopsy and RUT(Rapid Urease Test) and or UBT (Urea Breath Test)

Secondary outcomes

1

Description

Helicobacter Pylori Infection eradication rate, Hybrid regimes complication rate and patient compliance.

Timepoint

12 weeks after initiation of therapy regimens

Method of measurement

Questionnaire and endoscopy and biopsy and or UBT (Urea Breath Test)

Intervention groups

1

Description

Intervention group (10 days hybrid regimen): Pantoprazole 40 mgr / twice daily for 10 days and Amoxicillin 1 gr every 12 hours for 10 days and Clarithromycin 500 mgr + Tinidazole 500 mgr every 12 hours for 5 days latter.

Category

Treatment - Drugs

2

Description

Control group (14 days hybrid regimen): (Pantoprazole 40mgr / BID for 14 days and Amoxicillin 1 gr twice every 12 hours for 14 days and Clarithromycin 500 mgr + tinidazole 500 mgr every 12 hours for 7 days latter.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Subspecialty Of TOBA clinic, Sari Emam Khomeni Hospital Endoscopic Ward

Full name of responsible person

DR Valizadeh Toosi

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Khazar Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Assistance, Mazandaran University Of Medical Sciences

Full name of responsible person

DrAhmad Ali Aenayati

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Moallem Square

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Sari

Grant name

اعتبارات پژوهشی دانشگاهی

Grant code / Reference number

10506

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Assistance, 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

Sari Emam Khomeni Hospital, Gastroenterology Research Center

Full name of responsible person

Seyed Mohammad Valizadeh Toosi

Position

Assitant Professor of GI Group , Gastroenterologist

Other areas of specialty/work

Person responsible for scientific inquiries

Contact

Name of organization / entity

Gastroenterology Research Center

Full name of responsible person

Seyed Mohammad Valizadeh Toosi

Position

Gastroenterologist

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Position

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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