

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the Efficacy of 14 days Reverse Hybrid Regimen and 14 days concomitant Therapy for HP eradication

Protocol summary

Summary

Specific aims: Determining the rate of HP eradication of two 14-day reverse hybrid regimes and 14-day concomitant regimens and comparing the rate of eradication of the two above regimens. hypothesis: The effectiveness of the 14-days reversed hybrid regimen in Helicobacter pylori eradication is close to that of the 14-days concomitant regimens. Compliance of patients with drug use is better in reversible hybrid groups and with fewer side effects than concomitant regimens. In this randomized clinical trial, a total of 260 patients with dyspepsia enrolled the study. endoscopic evaluation was done and have indication for helicobacter pylori eradication. this patients dont received HP eradication regimens Previously . all patients entered the study in two groups. Patients are randomly assigned to two subgroups. In Group A (reverse hybrid group): patients in the first 7 days of treatment receive pantoprazole 40 mg, amoxicillin 1g, clarithromycin 500 mg, metronidazole 500 mg every 12 hours, and the second 7 days, clarithromycin and metronidazole were interrupted and only Pentoprazole and amoxicillin are continued at the same dose. Group B (14 days concomitant group): four drugs: pantoprazole 40 mg, amoxicillin 1g, clarithromycin 500 mg and metronidazole 500 mg every 12 hours for 14 days prescribed. The results of the study are then analyzed statistically

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081215510N3**

Registration date: **2017-09-24, 1396/07/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-24, 1396/07/02

Registrant information

Name

Seyed Mohammad Valizadeh Toosi

Name of organization / entity

Mazandaran University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3320 2242

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Recruitment status

Recruitment complete

Funding source

The financial source of the study is through the Deputy of Technology of Mazandaran University of Medical Sciences.

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Efficacy of 14 days Reverse Hybrid Regimen and 14 days concomitant Therapy for HP eradication

Public title

Comparing the Efficacy of 14 days Reverse Hybrid Regimen and 14 days concomitant Therapy for HP eradication

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with endoscopic findings of gastric or duodenal ulcer or gastric and duodenal erosoin and have 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 (poroton poup 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: **260**

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

Technology deputy, Mazandaran University Of
Medical Sciences

Street address

Moallem Squire

City

Sari

Postal code

324776119

Approval date

2017-11-22, 1396/09/01

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1396.2982

Health conditions studied

1

Description of health condition studied

Gastric Ucer

ICD-10 code

K25

ICD-10 code description

gastric ulcer

Primary outcomes

1

Description

Helicobacter pylori infection

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Upper GI endoscopy and biopsy for pathology and RUT for HP infection before intervention and endoscopy and biopsy or urea breath test and or stool examination for HP antigen for HP infection after intervention

Secondary outcomes

1

Description

HP eradication rate and drug adverse effects and patients compliance in two groups

Timepoint

12 weeks after initiation of therapautic regimens

Method of measurement

Urea breath test, stool exam for HP antigen and or endoscopy and biopsy. questionnaire assesment

Intervention groups

1

Description

In intervention group (reverse hybrid group): patients in the first 7 days of treatment receive pantoprazole 40 mg, amoxicillin 1g, clarithromycin 500 mg, metronidazole 500 mg every 12 hours, and the second 7 days, clarithromycin and metronidazole were interrupted and only Pentoprazole and amoxicillin are continued at the same dose.

Category

Treatment - Drugs

2

Description

In control group: (14 days concomitant group): four drugs: pantoprazole 40 mg, amoxicillin 1g, clarithromycin 500 mg and metronidazole 500 mg every 12 hours for 14 days prescribed.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Subspecialty of Toba clinic, Sari Imam Khomeni Hospital Endoscopy Ward

Full name of responsible person

DR Seyed Mohammad Valizadeh Toosi

Street address

Khazar Blvd.

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Technology Assistant, Mazandaran University Of Medical Sciences

Full name of responsible person

Dr Ahmad Ali Enayati

Street address

Moallem Square

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Technology Assistant, 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

Gut and Liver research Center, Mazandaran University Of Medical Sciences

Full name of responsible person

Seyed Mohammad Valizadeh Toosi

Position

Assitant Professor of Gastroenterology, Gastroenterologist

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