Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Erosiove 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. - Poroton poup inhibitor or antibiotics comsumption 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 seconed 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 seconed 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

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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 erosoin ; 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: **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 Squre
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 thrapy 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
Street address
Khazar Blvd.
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SARI

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Assistance, Mazandaran University Of Medical Sciences
Full name of responsible person
DrAhmad Ali Aenayati
Street address
Moallem Square
City
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
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Seyed Mohammad Valizadeh Toosi
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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