Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of treatment success rates in 10-day sequential therapies compare with 14-day standard therapy for Helicobacter pylori

Protocol summary

Summary

Aim: Success rates of 10-day sequential therapies of gastric Helicobacter pylori infection will compare with 14-day standard therapy of that. Methods and materials: through a longitudinal clinical trial, about 200 patients with helicobacter pylori gastritis or peptic ulcer for treatment divided in two groups of control and trial. The trial group treated with sequential regime and control group treated with standard regime of helicobacter pylori treatment. Four weeks after finishing of treatment patients should undergo urease breathing test and after that all data should be analyzed and written. Inclusion criteria: All patients admitted to the infectious diseases clinics in Firuzgar hospital older than seventeen years; in presence of H. pylori gastritis or peptic ulcer that establish by specimens obtained by endoscopy and rapid urease test. Exclusion criteria: The patients had not to be pregnant or lactating women, having chronic illness, such as cancer (Especially gastrointestinal cancer) , liver and kidney failure, positive history of antibiotic use in the two weeks prior to admission and no history of allergy to the antibiotics of our study. Interventions: Trail group is treated with pantaprazole once a day for five days and amoxicillin 1 g twice a day and next 5 days they treated with the same dose of pantaprazole and levofloxacin 500 mg daily and tinidazole 500 mg twice a day and control group treated 14 days with pantaprazole 40 mg daily, clarithromycin 500 mg twice a day, amoxicillin 1 g twice a day and metronidazole 500 mg twice a day. Main goal variable: Positive or negative results of urease breath test

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042817474N1**
Registration date: **2015-02-28, 1393/12/09**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-02-28, 1393/12/09

Registrant information

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Marzieh Daneshbodi
Name of organization / entity
Iran University of Medical Sciense
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor research of Iran university of medical science

Expected recruitment start date

2014-08-06, 1393/05/15

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of treatment success rates in 10-day sequential therapies compare with 14-day standard therapy for Helicobacter pylori

Public title

Evaluation of treatment success rates in 10-day sequential therapies compare with 14-day standard

therapy for Helicobacter pylori

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients over seventeen years, admitted to the infectious diseases clinics in Firoozgar hospital; the presence of H. pylori in the presence of gastritis or peptic ulcer specimens obtained by endoscopy and rapid urease test. Exclusion criteria: pregnant or lactating women; having chronic illness, such as cancer (Especially gastrointestinal cancer) , liver and kidney failure; positive history of antibiotic use in the two weeks prior to admission; no history of allergy to the antibiotics studied.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

1

Registry name

no registration

Secondary trial Id

no registration

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical ethic commitee of Iran University of Medical Sciense

Street address

Hemmat High Way,Cross Chamran Highway

City

Tehran

Postal code

Approval date

2014-07-06, 1393/04/15

Ethics committee reference number

93/5/105/1682

Health conditions studied

1

Description of health condition studied

Helicobacter pylori

ICD-10 code

B98.0

ICD-10 code description

Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

Primary outcomes

1

Description

Urease Breath Test

Timepoint

one month after finishing of treatment

Method of measurement

The presence of H. pylori in the stomach by using carbon 13-labeled urea fed to the patient and the patient's breathing carbon measurement

Secondary outcomes

empty

Intervention groups

1

Description

Trial group treated with pantaprazole once a day for five days and amoxicillin 1 g twice a day and next 5 days they treated with the same dose of pantaprazole and levofloxacin 500 mg daily and tinidazole 500 mg twice the days.

Category

Treatment - Drugs

2

Description

group II (control) treated with pantaprazole 40 mg daily, clarithromycin 500 mg twice a day and amoxicillin 1 g twice a day and metronidazole 500 mg twice a day for 14 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firuzgar hospital

Full name of responsible person

Dr.Marzieh Daneshbodi

Street address

Valiasr squere, Valadi street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Iran University of Medical Sciences

Full name of responsible person

Dr Mousavi

Street address

Library of medical univercity, Hematt Highway cross ChamranHighway

City

Tehran

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,Iran 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

Medical university of Iran university

Full name of responsible person

Marzieh Daneshbodi

Position

Doctorate/ Internal medicine resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Iran university of medical science

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specialist

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Internal medicine resident

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