

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparison of standard triple therapy with sequential therapy With base of levofloxacin and tinidazole in eradication of Helicobacter Pylori in patients with duodenal ulcer

Protocol summary

Summary

This study is a prospective and randomized double-blind clinical trial. The aim of this study is comparison of standard triple therapy with sequential therapy with base of levofloxacin and tinidazole in eradication of helicobacter pylori in patients with duodenal ulcer. Total of sample size is 168 patient with ages: 20-70 years old. The patients with a history of treatment of Helicobacter pylori, taking antibiotics, history of total gastrectomy, liver cirrhosis and uremia will be excluded. The patients are randomly divided into two groups with table of random numbers by computer. Assessor of results and patients do not know about the protocol of the study. First group, the first five days, receives pantoprazole, 40 mg twice daily, plus amoxicillin, 1 gm twice daily and the next five days receives pantoprazole, 40mg twice daily, levofloxacin 500 mg twice daily and tinidazole 500 mg twice daily. The second group as a control group receives omeprazole, 20 mg plus amoxicillin 1gr and clarithromycin 500 mg (All three drugs twice daily) for 10 days. Patients basic information such as age and sex, stature, Smoking, use of nonsteroidal antiinflammatory drug, alcohol intake, history of drug abuse will be recorded in both groups before treatment. Urea breath test results with c14 and endoscopy to check for Helicobacter pylori infection will be recorded in both groups before treatment and 8 week after completion of treatment period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110124823N1**

Registration date: **2015-12-24, 1394/10/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-24, 1394/10/03

Registrant information

Name

Shahram Hamedifar

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor For Research Of Ahvaz Jundishapur

Expected recruitment start date

2015-10-18, 1394/07/26

Expected recruitment end date

2016-03-16, 1394/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of standard triple therapy with sequential therapy With base of levofloxacin and tinidazole in eradication of Helicobacter Pylori in patients with duodenal ulcer

Public title

The effect of taking antibiotic on treatment of Helicobacter pylori infection

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: Patients with symptoms of dyspepsia, epigastric pain, nausea, vomiting, melena, hematemesis; Patients with duodenal ulcer; Patients with ages: 20-70. Exclusion Criteria: History of treatment of Helicobacter pylori; taking antibiotics; history of previous surgery on the stomach like total gastrectomy and gastrojejunostomy; history of drug allergies; liver cirrhosis; uremia; pregnancy.

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **168**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Drug compliance and complications are checked every three days. Acceptable compliance is defined as taking at least 70% of prescribed drugs. Complications is classified as follows: None or mild (creation discomfort without interfering with life activities), moderate (moderate discomfort that causes interference in life but continue treatment) and severe (leading to drug discontinuation by the patient).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University Of Medical Sciences

Street address

Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd., Ahvaz

City

Ahvaz

Postal code

Approval date

2015-10-17, 1394/07/25

Ethics committee reference number

IR.AJUMS.REC.1394.401

Health conditions studied

1

Description of health condition studied

Duodenal ulcer

ICD-10 code

K26

ICD-10 code description

erosion (acute) of duodenum, ulcer (peptic): duodenal-postpyloric

2

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

Helicobacter pylori infection

Timepoint

Before treatment and 8 week after completion of treatment

Method of measurement

Urea breath test with C14

2

Description

Helicobacter pylori infection

Timepoint

Before treatment and 8 week after completion of treatment

Method of measurement

Endoscopy

Secondary outcomes

1

Description

Nausea and vomiting

Timepoint

Every three days during treatment period

Method of measurement

Verbal questionnaire and the patient's response

2

Description

Abdominal pain
Timepoint
Every three days during treatment period
Method of measurement
Verbal questionnaire and the patient's response

3

Description
Watery diarrhea
Timepoint
Every three days during treatment period
Method of measurement
Verbal questionnaire and the patient's response

4

Description
Secretion or vaginal itching
Timepoint
Every three days during treatment period
Method of measurement
Verbal questionnaire and the patient's response

Intervention groups

1

Description
Group I (Intervention group): Patients, the first five days, receives pantoprazole, 40 mg twice daily, plus amoxicillin, 1 gm twice daily and the next five days receives pantoprazole, 40mg twice daily and levofloxacin 500 mg twice daily and tinidazole 500 mg twice daily.
Category
Treatment - Drugs

2

Description
Group II (Control group): Patients receives omeprazole, 20 mg plus amoxicillin 1gr and clarithromycin 500 mg (All three drugs twice daily) for 10 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khomeini Hospital
Full name of responsible person
Pezhman Alavinezhad
Street address
Khomeini Hospital, Shahid Ahvazian St., Ahvaz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Nader Saki
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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 Of Ahvaz Jundishapur 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
Ahvaz Jundishapur University of Medical Sciences
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Person responsible for scientific inquiries

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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