Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 levofloxacinand 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)
Phone
+98 61 3222 2922
Email address
hamedifar.sh@ajums.ac.ir

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): Pateints 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

City

Ahvaz

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

Street address

Vice chancellor For Research Of Ahvaz Jondishapour University of Medical Sciences, Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

City

Ahvaz

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

Full name of responsible person

Shahram Hamedifar

Position

Resident of Internal Medicine

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

City

Ahvaz

Postal code

Phone

+98 61 3222 2922

Fax

Email

drshahramhamedifar@gmail.com

Web page address

-

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person
Abdolrahim Masjedizadeh

Position
Subspeciality Gastroenterology and Hepatology

Other areas of specialty/work

Street address
Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

City
Ahvaz

Postal code
-

Phone
+98 61 3222 2922

Fax

Email
rmasjedi@hotmail.com

Web page address
-

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person
Sanaz Nazari

Position
Nurse Anesthesia

Other areas of specialty/work

Street address
Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

City
Ahvaz

Postal code
-

Phone
+98 61 3222 2922

Fax
-

Email
s.nz1990@yahoo.com

Web page address

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