Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Efficacy of helicobacter pylori eradication in Gastrointestinal side effects of aspirin and clopidogrel in patients with acute coronary syndrome

Protocol summary

Summary

The design objective of this study was to evaluate the effect of Helicobacter pylori eradication in reducing gastrointestinal bleeding in patients under treatment with aspirin and clopidogrel. Inclusion criteria included patients receiving the theraputic regimen of aspirin and clopidogrel in acute coronary syndrome and positive Helicobacter pylori stool antigen test. Exclusion criteria included a history of gastrointestinal bleeding, history of Helicobacter pylori eradication, pregnancy, cirrhosis, Patients with any medical history of any malignancy, history of peptic disease proven by endoscopy, acute or chronic renal failure, decompensated heart failure, and other serious health conditions. After the initial assessment, one hundred and forty patients were randomly divided into treatment and control groups. The two groups are matched in terms of factors such as age, sex, underlying disease (diabetes, hypertension), type of acute coronary syndrome, history of aggressive medical intervention (coronary stenting with balloon angioplasty), smoking and corticosteroid consumption. Patients in the control group received only pantoprazole and placebo while treatment group, received Standard Triple-Drug Therapy for Helicobacter pylori Eradication including amoxicillin, clarithromycin and pantoprazole over ten days. After 4 weeks of eradication therapy by stool antigen test, patients in the treatment group are examined. Once eradication is confirmed, Patients will be assessed quarterly for gastrointestinal bleeding. Deaths due to cardiovascular events or gastrointestinal complications are recorded. After three months, patients of both groups are compared. The primary objective was to reduce gross gastrointestinal bleeding and decreasing gastrointestinal symptoms such as dyspepsia, heart failure or recurrent thrombotic events during the study period were selected as secondary targets.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014081814190N5**
Registration date: **2014-09-06, 1393/06/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-09-06, 1393/06/15

Registrant information

Name
Mohammad Bahadoram
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 61 1374 3011
Email address
bahadoram.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology Development-Ahvaz Jondishapur University of Medical Sci

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Efficacy of helicobacter pylori eradication in Gastrointestinal side effects of aspirin and clopidogrel in patients with acute coronary syndrome

Public title
Efficacy of helicobacter pylori eradication in Gastrointestinal side effects in patients with acute coronary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patients receiving the therapeutic regimen of aspirin and clopidogrel in acute coronary syndrome; positive Helicobacter pylori stool antigen test.
Exclusion criteria: history of gastrointestinal bleeding; history of Helicobacter pylori eradication; pregnancy; cirrhosis; Patients with any medical history of any malignancy; history of peptic disease proven by endoscopy; acute or chronic renal failure; decompensated heart failure; other serious health conditions.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Ahvaz Jundishapur University of Medical Sciences, University City, Ahvaz

City
Ahvaz

Postal code

Approval date
2013-08-23, 1392/06/01

Ethics committee reference number
ajums.REC.1393.38

Health conditions studied

1

Description of health condition studied
Acute coronary syndrome

ICD-10 code
I24.9

ICD-10 code description
Acute ischaemic heart disease, unspecified

Primary outcomes

1

Description
gross gastrointestinal bleeding

Timepoint
Three months after the end of treatment

Method of measurement
using a questionnaire

Secondary outcomes

1

Description
Dyspepsia

Timepoint
Three months after the end of treatment

Method of measurement
using a questionnaire

2

Description
Thrombotic events

Timepoint
Three months after the end of treatment

Method of measurement
using a questionnaire

Intervention groups

1

Description
Intervention group: Amoxicillin 1 gram twice daily + Clarithromycine 500 mg twice daily + Pantoprazol 40 mg twice daily + Garlic daily

Category
Treatment - Drugs

2

Description

Control group: Patients received Pelasebo + Pantoprazol 40 mg twice daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hospital

Full name of responsible person

Dr. Abdol Rahim Masjedizadeh

Street address

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology Development-Ahvaz Jondishapur University of Medical Sci

Full name of responsible person

Dr. Nader Saki

Street address

Ground Floor, Faculty of Rehabilitation Sciences ,Ahvaz Jundishapur University of Medical Sciences, 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 and Technology Development-Ahvaz Jondishapur University of Medical Sci

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

Dr. Arman Shahriari

Position

Internal Medicine Resident

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of Medical Sciences, University City, Ahvaz Ahvaz

City

Ahvaz

Postal code

Phone

+98 61 1336 7543

Fax

Email

armanshahriari@yahoo.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

Dr. Abdol Rahim Masjedizadeh

Position

Association professor at Gastroenterology and Endoscopy

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of Medical Sciences, University City, Ahvaz

City

Ahvaz

Postal code

Phone

+98 61 1336 7543

Fax

Email

rahim.masjedi@gmail.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

Mohammad Bahadoram

Position

Medical Student

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of Medical Sciences, University City, Ahvaz

City

Ahvaz

Postal code

Phone

00

Fax

Email

mohammadbahadoram@yahoo.com;

bahadoram.m@ajums.ac.ir

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