

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of *Helicobacter pylori* eradication on recovery of platelet level in Idiopathic Trombocytopenic purpura patients

Protocol summary

Summary

The main aim of this study is evaluation of *Helicobacter Pylori* eradication in increasing of platelet count in Idiopathic thrombocytopenic purpura patients in comparison to placebo. Adult with Idiopathic thrombocytopenic purpura that their *Helicobacter Pylori* serology is positive ,coming to this study and if they had past history of gastrectomy or treatment of *Helicobacter Pylori* excluded from study . The population of our study are Idiopathic thrombocytopenic purpura patients, that coming to Babol University of Medical Sciences' clinics and volume of our samples is 30 patients. In this study *Helicobacter Pylori* eradication will be performed by Clarithromycin and Amoxicillin for 2 weeks and the time of study is from 2012 to unlimit time that our case will be enough. Out first outcome is increasing platelet count in patient comparison with placebo.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202098968N1**

Registration date: **2012-12-15, 1391/09/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-15, 1391/09/25

Registrant information

Name

Mostafa Javanian

Name of organization / entity

Babol University of Medical Sciences-Tropical And Infectious diseases research center

Country

Iran (Islamic Republic of)

Phone

+98 11 1219 0624

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of *Helicobacter pylori* eradication on recovery of platelet level in Idiopathic Trombocytopenic purpura patients

Public title

The effect of *Helicobacter pylori* eradication on recovery of platelet level in Idiopathic Trombocytopenic purpura patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusive Criteria: Adult with diagnosis of idiopathic thrombocytopenic purpura; *H. pylori* stool antigen test Positive or positive urease breath test Exclusive Criteria: Family history of gastric cancer;History of treatment of *H.Pylori* infection; History of ulcer or inflammation in stomach or Duodenum.

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

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

Babol University of Medical Sciences

Street address

Ganj Afrouz Avenue, Babol, Mazandaran

City

Babol

Postal code

Approval date

2012-05-26, 1391/03/06

Ethics committee reference number

30/6432/پ/ژ

Health conditions studied

1

Description of health condition studied

thrombocytopeny

ICD-10 code

D69.3

ICD-10 code description

Idiopathic thrombocytopenic purpura

Primary outcomes

1

Description

platelet count over than 100000

Timepoint

day 0,10,30,60,90,120,150,180 after drug

Method of measurement

Laboratory

Secondary outcomes

1

Description

Efficacy of treatment in eradication of H-Pylori

Timepoint

during 6 months(in days 0,10,30,60,90,120) after drug

Method of measurement

Laboratory

Intervention groups

1

Description

Intervention:clarithromycin 500 mg ,Amoxicillin 1000 mg, Omeprazol 20 mg /PO/ BD.

Category

Treatment - Drugs

2

Description

Control group:Treatment with Placebo twice a day for 14 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rohani Hospital

Full name of responsible person

Street address

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Full name of responsible person

DR. Amrollah Mostafazadeh

Street address

Vice Chancellor for Research and Technology, Babol University of Medical Sciences, Ganjafroz Avenue

City

Babol

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, Babol 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

Tropical and infectious diseases research center,
Babol University Of Medical Sciences

Full name of responsible person

Babak Yeganeh

Position

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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