

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The Comparison of Helicobacter Pylori eradication on the level of platelet in chronic Idiopathic Thrombocytopenic Purpura patients

Protocol summary

Summary

First of all we select the patients with ITP(platelet<150000 and minimum time is 6 month) whom come to Dr. Mohammad kermanshahi hospital. Then we check up helicobacter infection by examining stool antigene (by Acon kit) so with permutation block methods patient with helicobacter pylori infection divided into intervention and control groups. We try that patients in each group with age and sex to be similar. The basic therapy of ITP (Glucocorticoids) gives to each group. In intervention group anti helicobacter regimen (omeperazole, clarithromycin, metronidazole) also gives. Then we study the eradication of helicobacter by stool antigen test. In this study we need 12 patients with helicobacter infection under anti helicobacter regimen and 12 patients with helicobacter infection do not receive anti helicobacter therapy. Then with completing the data form and statistics search we compare the effect of helicobacter eradication at platelet condition in ITP patients (until 3 months after treatment monthly). Also, considering ITP is a chronic disease based on physician emphasizes the consumption of drug will control.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201603077677N4**

Registration date: **2016-08-28, 1395/06/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-28, 1395/06/07

Registrant information

Name

Mohamadreza Golpayegani

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 6331

Email address

golpayegani@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2015-10-07, 1394/07/15

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of Helicobacter Pylori eradication on the level of platelet in chronic Idiopathic Thrombocytopenic Purpura patients

Public title

The effect of Helicobacter Pylori eradication on the level of platelet in chronic Idiopathic Thrombocytopenic Purpura patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: platelet level < 150000 and time of ITP > 6 months; rule out other causes decreasing platelet level; helicobacter pylori infection that diagnosed by

stool anti-gene test.

Age

From **11 months** old to **17 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kemanshah University of Medical Sciences

Street address

Building No.2, Kemanshah University of Medical Sciences, Shahid Beheshti blvd., Kermanshah

City

Kermanshah

Postal code

Approval date

2016-02-03, 1394/11/14

Ethics committee reference number

IR.KUMS.REC.1394.329

Health conditions studied

1

Description of health condition studied

chronic idiopathic thrombocytopenic purpura

ICD-10 code

D69.3

ICD-10 code description

Idiopathic Thrombocytopenic purpura

Primary outcomes

1

Description

Platelet level

Timepoint

Before intervention, 1 month, 2 months and 3 months after intervention.

Method of measurement

Blood platelet level (CBC)

Secondary outcomes

empty

Intervention groups

1

Description

tab metronidazole 500mg each 12h tab clarithromycine 500 or 250 mg each 12h tab omeperazole 20 mg each 12h duration of treatment is 3 weeks(21 days)

Category

Treatment - Drugs

2

Description

in control group according to the coordination with pharmacy company and gastroenterologist the placebo therapy will give

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Mohammad Kermanshahi hospital

Full name of responsible person

Street address

Dr. Mohammad Kermanshahi hospital, Red Crescent crossroad, Kermanshah

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Behrooz Hamzeh

Street address

Building no.2 of kums-shahid beheshti blvd.-kermanshah

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Golpayegani

Position

Hematologist and oncologist

Other areas of specialty/work**Street address**

Dr. Mohammad Kermanshahi hospital, Red Crescent crossroad, Kermanshah

City

Kermanshah

Postal code**Phone**

+98 83 3721 8207

Fax**Email**

golpayegani@kums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Golpayegani

Position

Hematologist and oncologist

Other areas of specialty/work**Street address**

Dr. Mohammad Kermanshahi hospital, Red Crescent crossroad, Kermanshah

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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