

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 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 (omeprazole, 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 who do not receive anti helicobacter therapy. Then with completing the data form and statistics search we compare the effect of helicobacter eradication on platelet condition in ITP patients (until 3 months after treatment monthly). Also, considering ITP is a chronic disease based on physician emphasis 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**

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**Full name of responsible person**

Dr. Mohammad Reza Golpayegani

**Position**

Hematologist and oncologist

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golpayegani@kums.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*