

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of the effect of Intravenous immunoglobulin and rhophylac in treatment of immune thrombocytopenic purpura

Protocol summary

Summary

Objectives: Immune thrombocytopenic purpura is a bleeding disorder in children that is characterized by thrombocytopenia, petechiae and purpura. Different mechanisms are involved in the pathophysiology of this disease. In addition to peripheral platelet destruction, impaired platelet production and megakaryocyte apoptosis in bone marrow are also involved in the pathophysiology. Intravenous immunoglobulin (IVIg) is the common treatment of the disease but because of its high cost, the patient should be hospitalized for some days. Infusion time is at least eight hours and also numerous complications including aseptic meningitis may occur following consumption. In contrast, Rhophylac has the least complications. Its prescription does not need hospitalization and the maximum duration of infusion is 10 minutes. In this study we compare these two medications in treatment of immune thrombocytopenic purpura. Design: Intermittent randomization, without placebo, including sixty children with immune thrombocytopenic purpura. Participants including major eligibility criteria: All children of 1-15 ages with acute or chronic immune thrombocytopenic purpura who have platelet counts below thirty thousands at the time of treatment. Intervention: IVIG, 1 gr/kg, 8 hours IV infusion, single dose. Rhophylac, 50 µg/kg, 15 minutes IV infusion with 100 ml normal saline, single dose. Main outcome measures: Platelet count, fever, hemolysis, allergic reaction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012102811289N1**

Registration date: **2013-12-13, 1392/09/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-13, 1392/09/22

Registrant information

Name

Peyman Azadmanesh

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3312 0180

Email address

dr.azadmanesh@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

All costs of this project will be financed by the Arak University of Medical Sciences, Vice Chancellor for Research.

Expected recruitment start date

2012-08-05, 1391/05/15

Expected recruitment end date

2014-04-09, 1393/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Intravenous immunoglobulin and rhophylac in treatment of immune thrombocytopenic purpura

Public title

Comparison of the effect of Intravenous immunoglobulin

and raphylac

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Age upper 1 year and lower 15 years old in patients with acute or chronic ITP 2. Platelets <30000 at the time of treatment 3. Patients entered in the study that parental consent was obtained Exclusion criteria: 1. Splenectomy patients 2. Hemoglobin below 10 g/dL 3. Patients who have been treated with IVIG or raphylac in the past three weeks 4. Patients with renal insufficiency 5. Total bilirubin above 2 mg per deciliter and higher than normal liver enzymes 6. Patients who have a positive direct Coombs test 7. Patients who are infected with HIV or hepatitis C or B 8. Patients with lupus erythematosus 9. Patients with cardiovascular disease 10. Rh-negative patients

Age

From **1 year** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Patients will randomly and intermittently (based on the entry of patients into the study, intermittently) divide into two groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran

City

Arak

Postal code

Approval date

2012-10-06, 1391/07/15

Ethics committee reference number

91-131-2

Health conditions studied

1

Description of health condition studied

Idiopathic thrombocytopenic purpura

ICD-10 code

D69.3

ICD-10 code description

Idiopathic thrombocytopenic purpura (Evans syndrome)

Primary outcomes

1

Description

platelet count

Timepoint

Sixth hour and days 3, 7, and 14 after treatment

Method of measurement

complete blood count

2

Description

fever

Timepoint

since 6 hours after infusion

Method of measurement

mercury thermometer

3

Description

hemolysis

Timepoint

6 hours after infusion

Method of measurement

complete blood count

4

Description

allergic reaction

Timepoint

6 hours after infusion

Method of measurement

clinical manifestations

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1. IVIG, 1 gr/kg, 8 hours IV infusion, single

dose.

Category

Treatment - Drugs

2

Description

Intervention 2. Rhophylac, 50 µg/kg, 15 minutes IV infusion with 100 ml normal saline, single dose.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir kabir hospital

Full name of responsible person

Dr Peyman Azadmanesh

Street address

Amirkabir Hospital. Parastar square. Arak. Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person

Dr Saeed Changizi Ashtiani

Street address

Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran

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Arak

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak University of Medical Sciences, Vice Chancellor for Research

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

Arak University of Medical Sciences

Full name of responsible person

Dr Peyman Azadmanesh

Position

Pediatric resident

Other areas of specialty/work

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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