

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

A Comparative evaluation between the efficacy of IVIG and Methylprednisolone in primary treatment of immune thrombocytopenic purpura in children: Randomized clinical trial

Protocol summary

Summary

This study aimed to compare the effect of IVIG and corticosteroids in immune thrombocytopenic purpura (ITP). In this double-blind randomized clinical trial 44 patients with ITP between 6 months to 8 years who referred to Shafa Hospital and platelets are below 20,000 are evaluate and the patients who have underlying cause for thrombocytopenia will be excluded. The patients will be divided into two groups of 22 individuals, the first group will be treated with IVIG (2 gr / Kg / day) and the second group will be treated with methylprednisolone at a dose of 20mg / kg / day. Then, the platelets of patients in the second and fifth days after treatment will be measured, and the increase in platelet of the two groups will be compared as an index.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121831456N1**

Registration date: **2017-05-04, 1396/02/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-04, 1396/02/14

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Deputy of Research and Development of Ahvaz Jundishapour University of Medical Sciences

Expected recruitment start date

2017-03-15, 1395/12/25

Expected recruitment end date

2017-05-05, 1396/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative evaluation between the efficacy of IVIG and Methylprednisolone in primary treatment of immune thrombocytopenic purpura in children: Randomized clinical trial

Public title

A Comparative evaluation between the efficacy of IVIG and Methylprednisolone in primary treatment of immune thrombocytopenic purpura in children.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: platelet count less than $20 \times 10^9/L$ ($20,000/L$); Isolated thrombocytopenia; increase number of megacaryocytes in an otherwise normal bone marrow: :Exclusion criteria: Bone marrow transplant; Systemic Lupus Erythematosus; Ant phospholipid Syndrome; Evans Syndrome; Leukemia; Myelophthisic Infiltration;

Myelodysplasia; Aplastic Anemia

Age

From **6 months** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not 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

Golestan.Ahvaz.Ahvaz Jundishapour University of Medical Sciences

City

Ahvaz

Postal code

6135715794

Approval date

2016-12-03, 1395/09/13

Ethics committee reference number

IR.AJUMS.REC.1395.549

Health conditions studied

1

Description of health condition studied

Idiopathic Thrombocytopenic Purpura

ICD-10 code

D69.3

ICD-10 code description

Evans Syndrome

Primary outcomes

1

Description

Blood Platelet

Timepoint

Two days after treatment . Five days after treatment

Method of measurement

Count of Platelets in blood microliter measured by Sysmex kx21

Secondary outcomes

empty

Intervention groups

1

Description

First group : Treatment by Intravenous Immunoglobulin (IVIG) , dosage 2gr/kg/day

Category

Treatment - Drugs

2

Description

Second group : Treatment by Methylprednisolone , dosage 20mg/kg/day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital of Ahvaz

Full name of responsible person

Babak Sandughchian Shotorbani

Street address

Post Box 3155.Golestan.Shafa Hospital.Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Development of Ahvaz Jundishapour university of Medical Sciences

Full name of responsible person

Behzad SHARIF MAKHMALZADEH

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City

Ahvaz

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research and Development of Ahvaz Jundishapur 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

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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