Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Efficacy of a single dose of Intravenous immune globulin (IVIG) (0.8 gr/Kg) vs tab Prednisolone (2mg/Kg) in pediatric newly diagnosed Immune thrombocytopenia (ITP)

Protocol summary

Study aim

Evaluation of the efficacy and safety of intravenous immunoglobulin and corticosteroid

Design

The current study is an open label phase 3 clinical trial with parallel groups in which 100 newly diagnosed immune thrombocytopenia with a platelet count <10,000/dl will be studied. Participants after including the study, will be divided in two groups using a simple random method. One group of patients will receive intravenous immunoglobulin and the other will receive corticosteroids. The platelets number will be measured in order to find the effectiveness of each group in three intervals, including 48 hours, 7 days and one month after injection.

Settings and conduct

The current trial will be performed at Mofid Hospital on ITP patients. The participants included in the study will then randomly divided into two groups. Participants in the first group will receive IVIG at a dose of 0.8 mg/kg and in the second group will receive prednisolone 2 mg per kilogram of weight for seven days. During hospitalization, signs of bleeding symptoms will be gathered from patients. All process will be under the supervision of a pediatric hematologist

Participants/Inclusion and exclusion criteria

The participants includes patients referred to Mofid Hospital with an age range between one month and 17 years, a diagnosis of Immune thrombocytopenia (ITP) and a platelet count of less than 10,000/dL. Also, if there is severe bleeding, history of splenectomy, contraindications to receiving IVIG, history of receiving IVIG or recent corticosteroids, sepsis, high fever, splenomegaly, or DIC, they will be excluded from the study

Intervention groups

Participants in the first intervention group will receive IVIG at a dose of 0.8 mg/kg and in the second intervention group will receive prednisolone 2 mg per kilogram of weight for seven days

Main outcome variables

Platelet count Bleeding symptom

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221206056735N1**
Registration date: **2022-12-19, 1401/09/28**
Registration timing: **prospective**

Last update: **2022-12-19, 1401/09/28**
Update count: **0**

Registration date

2022-12-19, 1401/09/28

Registrant information

Name

Masoud Khodaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-06-21, 1402/03/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of a single dose of Intravenous immune globulin (IVIG) (0.8 gr/Kg) vs tab Prednisolone (2mg/Kg) in pediatric newly diagnosed Immune thrombocytopenia (ITP)

Public title
Evaluation of intravenous immunoglobulin versus corticosteroid in immune thrombocytopenic purpura
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of participants between one month and 17 years diagnosis of ITP The patient's plasma platelets are less than 10,000 per deciliter
Exclusion criteria:
Life-threatening bleeding History of splenectomy Any contraindications for receiving IVIG A history of receiving IVIG or corticosteroids in the last two weeks (platelets have not reached more than 50,000) Presence of co-morbidity such as sepsis Fever above 38.5 degrees Celsius Splenomegaly (the edge of the spleen two centimeters below the edge of the rib) Presence of disseminated intravascular coagulation (DIC) (i.e., fibrinogen < 1 along with elevated D-dimer)
Age
From **1 month** old to **17 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients included in the study will be entered in two blocks, one group will receive intravenous immunoglobulin and the other will receive corticosteroids. In block dividing, we will ensure that exactly the same number of participants enter both of our intervention groups in consecutive but equal time intervals. However, in this study, due to the use of two blocks, there will be no possibility of blinding the information of some participants. Randomization in this study is done by a researcher in a simple random method. In this way, every new patient included in the study will enter one of the intervention groups randomly (using a lion coin or a line) and the next participant will enter the opposite group. The advantage of this method is the uniform distribution of participants in both groups both in terms of time and causes that there are not more participants in a certain group in a certain period of time. Also, if there is a lack of sample size in the sampling interval, it guarantees the equal number of people in the two groups.
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
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Tehran, Velengak, Koodakyar st
City
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Province
Tehran
Postal code
1985717443
Approval date
2022-12-01, 1401/09/10
Ethics committee reference number
IR.SBMU.MSP.REC.1401.437

Health conditions studied

1

Description of health condition studied
Immune thrombocytopenic purpura (ITP)
ICD-10 code
D69.3
ICD-10 code description
Immune thrombocytopenic purpura

Primary outcomes

1

Description
Platelet count
Timepoint
The platelet count will be measured within three intervals: 48 hours, 7 days and one month after IVIG injection.
Method of measurement
Cell blood count

Secondary outcomes

1

Description
Bleeding symptoms
Timepoint
During hospitalization
Method of measurement
Questionnaire and physical examination by pediatric hematologist

Intervention groups

1

Description
Intervention group: group receiving intravenous immunoglobulin: In this group, participants receive intravenous immunoglobulin at a dose of 0.8 mg per kilogram of the patient's weight naturally. The infusion will be done slowly and over at least 4 to 6 hours.
Category
Treatment - Drugs

2

Description
Intervention group: Corticosteroid group: In this group, the participants will receive corticosteroids in the form of prednisolone 2 mg per kilogramfor at least 7 days or more according to the patient's medical discretion.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mofid Children's Hospital
Full name of responsible person
Dr. Masoud Khodaei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Masoud Khodaei
Position
Resident
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The data of this article will be published in two ways. First of all, after the publication of the thesis of this article, it will be in the Research Vice-Chancellor of Shahid Beheshti University of Medical Sciences. Then an article from this data will be published in one of the domestic and foreign journals that will be available for public.
When the data will become available and for how long
There will be no time limit on data access.
To whom data/document is available
The data will be available for public access.
Under which criteria data/document could be used
Data reanalysis will not be allowed under any circumstances.
From where data/document is obtainable
To receive data and documents, send a message to the responsible author. Requests will only be answered via email. Applicants can send their application to the email address surgery1353@gmail.com.
What processes are involved for a request to access data/document
After sending the request to the responsible author's e-mail, he will review it in general. Then, if there is no conflict of interest, all authors and researchers of the project will be informed. If the team agrees, the data will be provided to the applicant.
Comments