

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

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Tehran, Velengak, Koodakyar st

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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 kilogram for 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

Medical doctor

Other areas of specialty/work

Pediatrics

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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