

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the Efficiency of Short-Term and Two-Week Oral Prednisolone Use to Manage Newly Diagnosed Immune Thrombocytopenia

Protocol summary

Study aim

Investigating the efficacy of short-term oral prednisolone compared to a two-week period in the treatment of newly diagnosed immune thrombocytopenic patients

Design

A clinical trial with a control group and a parallel group, which phase 3 was conducted on 70 non-randomized patients.

Settings and conduct

Mofid Children's Hospital Loghman Hakim Hospita

Participants/Inclusion and exclusion criteria

Patients who have suffered from immune thrombocytopenic disease in less than 3 months Platelet count less than 20×10^9 per liter Age between 1 month and 14 years

Intervention groups

Investigating the effect of short-term corticosteroids in patients with immune thrombocytopenia compared to the effect of long-term and two-week corticosteroids in these patients

Main outcome variables

The count of Platelets in patients one month after taking prednisolone for one week The patients go into remission after taking one week of prednisolone

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230718058831N1**

Registration date: **2023-10-28, 1402/08/06**

Registration timing: **retrospective**

Last update: **2023-10-28, 1402/08/06**

Update count: **0**

Registration date

2023-10-28, 1402/08/06

Registrant information

Name

Khatere Tavajohi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 7021

Email address

khtavajohi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-09-11, 1402/06/20

Actual recruitment start date

2022-10-07, 1401/07/15

Actual recruitment end date

2023-07-11, 1402/04/20

Trial completion date

2023-07-11, 1402/04/20

Scientific title

Comparison of the Efficiency of Short-Term and Two-Week Oral Prednisolone Use to Manage Newly Diagnosed Immune Thrombocytopenia

Public title

short term prednisolon in itp

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

childeren with acutelImmune Thrombocytopenia

Exclusion criteria:

Patients with active infections and septicemia patients with positive antinuclear antibody patients with Evans syndrome Patients with chronic immune thrombocytopenia Patients with positive glue culture

Age

From **1 month** old to **14 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Not 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**

Ethics Committee of Medical Students of Shahid Beheshti University of Medical Sciences

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No 4 . four baharestan,pasdaran blvd,tehran town

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1689887961

Approval date

2023-06-27, 1402/04/06

Ethics committee reference number

IR.SBMU.MSP.REC.1402.177

Health conditions studied**1****Description of health condition studied**

Treatment Patients with acute immune thrombocytopenia

ICD-10 code

D69.3

ICD-10 code description

Immune thrombocytopenic purpura

Primary outcomes**1****Description**

Platelet count of patients after a short course of prednisolone

Timepoint

Comment on the number of blood platelets at different time points before the start and days 2, 7, 30 and 60 after the start of the treatment period

Method of measurement

Complete blood count

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group:The study is designed in the form of a coincidental and open label. All patients with a newly diagnosed immune thrombocytopenic condition were aged 1 month to 15 years and had a platelet count of less than 109×20 per liter after obtaining informed consent from the parent Sadfi ward group took cannnde long short duration prednizolon diet With a daily dosing regimen of 2 mg/kg of oral prednisolone on days 1 to 7 without drug dose titration, platelets were weighed during treatment on days 3, 14 and 30 during blood cell count testing. Similarly, 2 months after the start of treatment, patients were examined and response to treatment was given. Patients could be excluded from the study in any time they chose.

Category

Treatment - Drugs

2**Description**

Intervention group: The study is designed as a randomized and open label format. All patients with a newly diagnosed immune thrombocytopenic condition were aged 1 month to 15 years and had a blood platelet count of less than 109×20 per liter after obtaining parental consent The group was given two weeks of dietary prednisolone .. Patients' platelets were measured before the start of the appointment and registration period and drugs were measured in mg/kg² on 14 days and then from days 14 to 21 doses and titration were performed. Platelet counts were performed on days 3, 14 and 30 during treatment. Similarly, 2 months after the start of treatment, patients were examined and response to treatment was given. Patients could be excluded from the study in any time they chose

Category

Treatment - Drugs

Country of origin**Type of organization providing the funding**

Persons

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mofid children hospital

Full name of responsible person

Shamsollah Noori poor

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info-mch@sbmu.ac.ir

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshim Zarghi

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No4 ,four Baharestan , Pasdaran blvd,Tehran town

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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

70

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Khatere Tavajohi

Position

Associate

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Resident

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Other areas of specialty/work

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Person responsible for updating data**Contact**

Name of organization / entity

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Other areas of specialty/work

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Fax**Email**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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 the study includes the complete information of the patients and the course of the patients' tests, and after deidentifying the individuals, a part of the data that is related to the outcome of the study can be published.

When the data will become available and for how long

6 month after published

To whom data/document is available

For other researchers

Under which criteria data/document could be used

For reference in other studies

From where data/document is obtainable

with researcher khatere tavajohi khtavajohi@gmail.com

What processes are involved for a request to access data/document

After submitting the request via email, information will be provided to them within 2 hours

Comments