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 x 109 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)
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+98 21 2222 7021
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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 acuteImmune 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

Street address
No 4 . four baharestan,pasdaran blvd,tehran town

City
Tehran

Province
Tehran

Postal code
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
Compelete 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 cannde 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

Recruitment centers

1

Recruitment center
Name of recruitment center
Mofid children hospital
Full name of responsible person
Shamsollah Noori poor
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Above hosseinieh ershad ,shariati blvd,tehran town
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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
Street address
No4 ,four Baharestan , Pasdaran blvd,Tehran town
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Province
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khtavajohi@gmail.com
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
Country of origin
Type of organization providing the funding
Persons

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 updating data

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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 mounth 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