Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 2026

Comparing the effects of three therapeutic regimens of oral prednisolone, intravenous methylprednisolone, and oral prednisolone plus recombinant human thrombopoietin on platelet increase in patients with primary immune thrombocytopenic purpura: a clinical trial study.

Protocol summary

Study aim

Comparative effect of three therapeutic methods of prednisolone combined with recombinant human thrombopoietin and prednisolone alone and pulse methylprednisolone alone as first line treatment in patients with primary immune thrombocytopenic purpura

Design

Randomized clinical trial work on 75 Mitla patients

Settings and conduct

In this study, the number of 75 patients with immune thrombocytopenic purpura who were diagnosed with ITP based on the existing symptoms and signs according to the international guidelines of the working group and are in the age range of 18 years and above, or people who have been diagnosed with ITP for three months and have platelets less than 30 x 10 9 / L or platelets above 30 x 10 9 / L with signs of bleeding based on the grading scores of bleeding symptoms will be included in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria include age 18-60 years, having a normal spleen size Patients with kidney failure, diabetes, pregnancy, secondary IIP (MDS, APS and collagen disease) and people who have taken drugs due to another disease in the last 3 months will be excluded from the study.

Intervention groups

The first group: they will receive pulse methylprednisolone 2-3 mg/kg intravenously for 3 days every 2 weeks for 4 weeks until re-examination. The second group: They will receive oral prednisolone tablets 1 mg/kg daily for 4-6 weeks until re-examination. The third group: the analogue of the human compound will receive 250 micrograms weekly subcutaneously for 4 weeks along with oral prednisolone tablets 0.5 mg/kg daily until re-examination.

Main outcome variables

High doses of corticosteroids have many and varied side effects, including headache, anorexia, weakness, and nausea. Cardiovascular symptoms, eye symptoms, metabolic symptoms, and an increase in the possibility of infections (4)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230717058813N1**
Registration date: **2023-09-22, 1402/06/31**
Registration timing: **prospective**

Last update: **2023-09-22, 1402/06/31**
Update count: **0**

Registration date

2023-09-22, 1402/06/31

Registrant information

Name

Reyhaneh Azimi Nobari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date
2025-02-18, 1403/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effects of three therapeutic regimens of oral prednisolone, intravenous methylprednisolone, and oral prednisolone plus recombinant human thrombopoietin on platelet increase in patients with primary immune thrombocytopenic purpura: a clinical trial study.

Public title
Comparing the effects of three therapeutic regimens prednisolone on platelet increase in patients with primary immune thrombocytopenic purpura

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
age of 18-60 years, having a normal spleen size suffering from Immune thrombocytopenia (ITP)

Exclusion criteria:
history of chronic kidney diseases history of diabetes pregnant women or pregnancy during study history of secondary Immune thrombocytopenia (ITP) such as (Antiphospholipid syndrome, Myelodysplastic syndromes and vasculitis) patients under treatment with any drugs within 3-month before participating in study

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
All eligible subjects will be randomly assigned to one of the three groups receiving prednisolone alone, prednisolone + recombinant human thrombopoietin, and pulse methylprednisolone alone with a ratio of 1:1:1. The randomization method will be permuted block randomization, which will be done in 7 blocks of sizes 6, 9, 12, 15 until the sample size is exhausted using "Ralloc" package in STATA software. Patients will be included in each group based on the determined sample size and based on the list of randomized individuals (along with a specific research code for each individual).

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 School of Medicine - Shahid Beheshti University of Medical Sciences

Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak,

City
Tehran

Province
Tehran

Postal code
1983969411

Approval date
2023-07-01, 1402/04/10

Ethics committee reference number
IR.SBMU.MSP.REC.1402.180

Health conditions studied

1

Description of health condition studied
primary immune thrombocytopenia purpura

ICD-10 code
D68

ICD-10 code description
Other coagulation defects

Primary outcomes

1

Description
Platelet value in cell blood count test

Timepoint
Monthly

Method of measurement
Cell blood count test

Secondary outcomes

1

Description
Side effect of treatment with corticosteroids

Timepoint

Six-months after treatment

Method of measurement

Clinical visit

Intervention groups

1

Description

The first group: they will receive pulse methylprednisolone 2-3 mg/kg intravenously for 3 days every 2 weeks for 4 weeks until re-examination.

Category

Treatment - Drugs

2

Description

Control group: They will receive oral prednisolone tablets 1 mg/kg daily for 4-6 weeks until re-examination.

Category

Treatment - Drugs

3

Description

Intervention group: The analog of the human compound will receive 250 micrograms weekly subcutaneously for 4 weeks along with oral prednisolone tablets 0.5 mg/kg daily until re-examination.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Reyhaneh Azimi Noubari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Afshin Zarghi

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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

Reyhaneh Azimi Noubari

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Farnaz Sabrian

Position
Assistant Professor of Internal Medicine

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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All patient information will be entered into the database (Excel format) and after checking the the outliers terms and data cleaning, it will be prepared for statistical analysis. The final data file will be provided to the research unit of internal diseases department to conduct further studies.

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Researchers in academic institutions

Under which criteria data/document could be used
If there is a positive outcome and to need for further studies in this field

From where data/document is obtainable
Dr. Rehane Azimi Nobari-Imam Hossein Hospital- internal disease clinics

What processes are involved for a request to access data/document
using application form in research unit of hospital

Comments