ISRCTN84894190 https://doi.org/10.1186/ISRCTN84894190

# Immune imbalance in pediatric persistent immune thrombocytopenia

**Submission date**
08/09/2025

**Recruitment status**
No longer recruiting

**Registration date**
11/09/2025

**Overall study status**
Completed

**Last Edited**
31/10/2025

**Condition category**
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
Immune thrombocytopenia (ITP) in children is an autoimmune disorder with an incompletely understood pathogenesis. Previous studies have implicated imbalances in T lymphocyte subsets, particularly increased T helper 17 (Th17) cells and decreased regulatory T cells (Tregs), in disease activity. Regulatory B cells (Bregs), which play a critical role in maintaining immune homeostasis, have also been proposed to contribute to ITP pathophysiology. This study aims to explore the dynamic alterations of T helper 17 (Th17) cells, regulatory T (Treg) cells and regulatory B (Breg) cells in children with persistent immune thrombocytopenia (ITP).

Who can participate?
Children with persistent ITP and age- and sex-matched healthy volunteers

What does the study involve?
Children with primary persistent ITP were enrolled in the ITP group, whereas age- and sex-matched healthy children undergoing physical examinations during the same period served as the control group. Patients in the ITP group received the following treatment upon confirmed diagnosis: intravenous immunoglobulin over 1–2 consecutive days; oral prednisone with a treatment course of 4–6 weeks (tapering was conducted gradually based on platelet recovery); additional IVIG doses were administered intermittently if the platelet count remained low or if active bleeding was present.

What are the possible benefits and risks of participating?
Children with persistent ITP have a slight recovery in immune function after treatment.

Where is the study run from?
The First Affiliated Hospital of Xinxiang Medical University (China)

When is the study starting and how long is it expected to run for?
October 2019 to December 2023

Who is funding the study?
The First Affiliated Hospital of Xinxiang Medical University (China)

Who is the main contact?
Peiling Li, lplli2020@21cn.com

# Contact information

### Type(s)
Public, Scientific, Principal investigator

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
Nil known

# Study information

### Scientific Title
Immune imbalance and dynamic characteristics of Th17, Treg and Breg cells in children with persistent immune thrombocytopenia

### Study objectives
To explore the dynamic alterations of T helper 17 (Th17) cells, regulatory T (Treg) cells and regulatory B (Breg) cells in children with persistent immune thrombocytopenia (ITP).

### Ethics approval required
Ethics approval required

### Ethics approval(s)
approved 25/11/2019, Ethics Committee of The First Affiliated Hospital of Xinxiang Medical University (No. 88 Jiankang Road, Weihui, 453100, China; +86 (0)373 4402155; xyyfyxx@163.com), ref: EC-019-133

### Study design

Prospective cohort study

### Primary study design
Observational

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Immune thrombocytopenia (ITP)

### Interventions
34 children with primary persistent ITP were enrolled in the ITP group, whereas 30 age- and sex-matched healthy children undergoing physical examinations during the same period served as control group.

The treatment protocol for the ITP group was as follows. Based on the Chinese Guidelines for the Diagnosis and Treatment of Childhood Primary Immune Thrombocytopenia (2019 Edition), patients in the ITP group received the following first-line therapy upon confirmed diagnosis:
1. Intravenous immunoglobulin – 0.8–1 g/kg/day, administered via intravenous infusion over 1–2 consecutive days
2. Prednisone – oral administration at 1.5–2 mg/kg/day (maximum daily dose: 60 mg), with a treatment course of 4–6 weeks (tapering was conducted gradually based on platelet recovery)
3. Supplemental therapy – additional IVIG doses (0.8 g/kg per administration) were administered intermittently if the platelet count remained <20 × $10^9$/L or if active bleeding manifestations were present

### Intervention Type
Drug

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
Intravenous immunoglobulin; prednisone

### Primary outcome(s)
Immune cell population (Th17 cell level, Treg cells, Breg cells) quantitatively analyzed and measured using BD FACSDx Flex TM flow cytometry at baseline and 3 months of treatment

### Key secondary outcome(s))
BD FACSDx FlexTM flow cytometry was used to analyze the proportion of Th17 / Treg and the proportion of Breg cells in CD19 / B lymphocytes at baseline and 3 months before and after treatment

### Completion date
31/12/2023

## Eligibility

## Key inclusion criteria
ITP group:
1. Patients meeting the diagnostic criteria for primary persistent ITP as outlined in the Chinese Guidelines for the Diagnosis and Treatment of Childhood Primary Immune Thrombocytopenia (2019 Edition), defined as a disease duration exceeding 3 months and a platelet count below 100 × $10^9$/L
2. Age ≤14 years at the time of enrolment
3. No prior treatment with glucocorticoids, intravenous immunoglobulin (IVIG) or immunosuppressive agents within 1 month before initiating study treatment
4. Availability of complete clinical data for analysis.

Control group:
The control group comprised healthy children undergoing physical examinations during the same period, matched by age and sex to the ITP group. The inclusion criteria were as follows:
1. Age difference within 1 year compared with ITP participants
2. Gender distribution matching that of the ITP group (male-to-female ratio: approximately 1.6:1)
3. Participants had no infections, vaccinations or intake of folic acid, vitamin B12 or vitamin B6 within 4 weeks prior to enrolment

## Participant type(s)
Patient

## Healthy volunteers allowed
No

## Age group
Child

## Upper age limit
14 years

## Sex
All

## Total final enrolment
60

## Key exclusion criteria
1. Presence of severe infections, haematologic malignancies or substantial hepatic or renal dysfunction
2. History of vaccination or blood transfusion within 4 weeks prior to enrolment
3. Secondary thrombocytopenia, including but not limited to systemic lupus erythematosus, antiphospholipid syndrome, drug-induced thrombocytopenia or Evans syndrome
4. Known or suspected primary immunodeficiency
5. History of haematopoietic stem cell transplantation
6. Refusal of informed consent by legal guardians

## Date of first enrolment
01/12/2019

## Date of final enrolment

30/06/2023

# Locations

### Countries of recruitment
China

### Study participating centre
**The First Affiliated Hospital of Xinxiang Medical University**
No. 88 Jiankang Road
Weihui
China
453100

# Sponsor information

### Organisation
First Affiliated Hospital of Xinxiang Medical University

### ROR
https://ror.org/0278r4c85

# Funder(s)

### Funder type
Government

### Funder Name
Henan Province Medical Science and Technology Research Program Joint Construction Project (LHGJ20200518)

# Results and Publications

### Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

### IPD sharing plan summary
Data sharing statement to be made available at a later date