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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
10/09/2025

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?
Shujun Li, ruolin2223@126.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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

Pharmaceutical study type(s)
Pharmacodynamic

Phase
Not Applicable

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

Primary outcome measure
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

Secondary outcome measures
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

Overall study start date
01/10/2019

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

Age group
Child

Upper age limit
14 Years

Sex
Both

Target number of participants
60

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

Sponsor details
No. 88 Jiankang Road
Weihui
China
453100

Sponsor type
Hospital/treatment centre

Website
http://www.xyyfy.com/

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2026

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