The role of B and T cells in ITP

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Investigate the relationship between disease activity in ITP and the phenotype and function of autoantigen-specific T cells and B cells.

Ethical review	Approved WMO
Status	Pending
Health condition type	Platelet disorders
Study type	Observational invasive

Summary

ID

NL-OMON52114

Source
ToetsingOnline

Brief title
B and T cells in ITP

Condition

- Platelet disorders
- Autoimmune disorders

Synonym
Immune Thrombocytopenia, ITP

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ReumaNederland LLP-16

Intervention

Keyword: B Lymphocytes, Immune Thrombocytopenia, T Lymphocytes

Outcome measures

Primary outcome

Changes in the auto-antigen specific response in relation to disease activity

Secondary outcome

Changes in auto-antibody characteristics in relation to disease activity

Function and phenotype of antigen-specific cells in relation to clinical

characteristics

Study description

Background summary

ITP is an autoimmune disease in which platelets and megakaryocyte destruction is mediated by autoantibodies. These autoantibodies are produced by plasma cells, derived from B cells, a process initiated by antigen-specific T cells. These antigen-specific T cells have been identified in the peripheral blood of ITP patients, yet it is unknown whether these cells are continuously maintaining the disease in the chronic phase. Treatments targeting T and B cells (e.g. rituximab, azathioprine, ciclosporine) are effective in ITP and therefore point towards a role for these lymphocytes in disease progression. Our lab has longstanding experience with investigations on antigen-specific cells.

We hypothesize that ITP disease activity is dependent on helper and regulatory autoantigen-specific T cells, controlling the B cell to plasma cell transition and autoantibody production.

Study objective

Investigate the relationship between disease activity in ITP and the phenotype and function of autoantigen-specific T cells and B cells.

Study design

In this observational cohort study, the blood collection time points and assays are as follows:
All included patients will be requested to donate 100ml of blood at inclusion

and thereafter once every year for a total duration of five years. The numbers and function of autoantigen-specific T cells and B cells will be compared between patient categories defined on the basis of clinical characteristics.

Relapsing or newly diagnosed ITP patients (i.e. with active disease) will be enrolled for collection of 50 ml of peripheral blood at four pre-defined time points: at relapse and after 1, 4 and 10 weeks. Autoantigen-specific responses will be compared between the time points.

Study burden and risks

Minimal to negligible. 50-100 mL of additional blood drawn per time point.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

diagnosed ITP

Exclusion criteria

Active, uncontrolled bleedings
Age <18

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	25-04-2022
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-05-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL78969.058.22