

Fatigue and function of platelets in patients with chronic ITP

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26409

Source

NTR

Brief title

PICI

Health condition

chronic ITP
platelet function
Immune thrombocytopenia
fatigue

Sponsors and support

Primary sponsor: University Medical Center Utrecht

Source(s) of monetary or material Support: Sponsor

Intervention

Outcome measures

Primary outcome

To assess platelet function and coagulation parameters in adult chronic ITP patients in relation to their bleeding phenotype

Secondary outcome

- To assess immune profiles in chronic ITP patients and explore for imbalances between effector cells and regulatory cells
- To validate the CIS-20 fatigue subscale in chronic ITP patients by comparing it to the FACIT-F
- To assess the prevalence of menorrhagia in female chronic IT patients and the impact on daily life
- To compare fatigue in chronic ITP patients with fatigue in healthy controls and other chronically ill patients

Study description

Background summary

In the current proposal, our primary objective is to study the platelet function and the correlation with bleeding phenotype in chronic ITP patients. This might add to platelet count alone in order to understand which patients are at risk of significant bleeding or need treatment. Secondary, we will assess imbalances in the patients' immunologic profiles in patients with chronic ITP, the extent of fatigue and menstrual problems and the internal consistency of the fatigue subscale of the CIS-20. These results will increase insight in which areas are feasible for future (interventional) research.

Study objective

In the current proposal, our primary objective is to study the platelet function and the correlation with bleeding phenotype in chronic ITP patients. This might add to platelet count alone in order to understand which patients are at risk of significant bleeding or need treatment. Secondary, we will assess imbalances in the patients' immunologic profiles in patients with chronic ITP, the extent of fatigue and menstrual problems and the internal consistency of the fatigue subscale of the CIS-20. These results will increase insight in which areas are feasible for future (interventional) research.

Study design

1 timepoint (cross-sectional study)

Intervention

An extra blood sample withdrawal during a routine venipuncture (as part of standard of care), the ITP-bleeding assessment tool (ITP-BAT) and two questionnaires. Women will be asked to

fill out an extra questionnaire regarding their menstruation and to count the use of sanitary pads and/or tampons during one month (PBAC).

Contacts

Public

Divisie Interne Geneeskunde en Dermatologie, Van Creveldkliniek, Universitair Medisch Centrum Utrecht, Huispostnummer C.01.428

Wobke Dijk, van
Postbus 85500

Utrecht 3508 GA
The Netherlands
0887567846

Scientific

Divisie Interne Geneeskunde en Dermatologie, Van Creveldkliniek, Universitair Medisch Centrum Utrecht, Huispostnummer C.01.428

Wobke Dijk, van
Postbus 85500

Utrecht 3508 GA
The Netherlands
0887567846

Eligibility criteria

Inclusion criteria

- Age 16 years and older
- Previously confirmed diagnosis of chronic primary ITP with current platelet counts of $<100 \times 10^9/L$ or currently on (any) treatment for chronic ITP
- Willing and able to understand the study information and sign the informed consent form.

Exclusion criteria

There are no additional exclusion criteria

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	02-04-2019
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	27-07-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52965
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7200
NTR-old	NTR7399
CCMO	NL66313.041.18
OMON	NL-OMON52965

Study results