Prospective multicenter cohort for evaluation of changes in Immune profile and platelet function after start of TPO-receptor agonist in patients with chronic ITP

Published: 27-02-2019
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To evaluate possible changes in immune profiles and platelet function after start of a TPO-RA.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Platelet disorders
Study type	Observational non invasive

Summary

ID

NL-OMON55371

Source
ToetsingOnline

Brief title
Changes in immune profiles and platelet function after start TPO-RA in ITP

Condition

- Platelet disorders
- Autoimmune disorders

Synonym
immune thrombocytopenia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Novartis

Intervention

Keyword: Eltrombopag, immune profiles, ITP, TPO-RA

Outcome measures

Primary outcome

monitor B and T cell profiles and changes in platelet function and reactivity

in adult patients with ITP who are treated with eltrombopag.

Secondary outcome

nvt

Study description

Background summary

It has been suggested that prolonged use of TPO-receptor agonists (TPO-RA) can result in immune tolerance induction in patients with ITP. However, little is known about the effect of this kind of immune modulation on B- and T-cell profiles in ITP. Furthermore, the use of TPO-RA is associated with an increased rate of thromboembolic events, suggesting the possibility that TPO-RA alters the platelet function. The aim of this study is to test our hypothesis that TPO-RA increases platelet activity and alters immune profiles in ITP.

Study objective

To evaluate possible changes in immune profiles and platelet function after start of a TPO-RA.

Study design

non-interventional, non-randomized, non-blinded, observational trial design.

Study burden and risks

At least four out of five times, the blood sample will be taken during a scheduled venipuncture, as part of standard of care. Because only a small volume will be withdrawn, the risk is considered negligible. Possibly, one extra venipuncture is necessary. Venipunctures are carried out very often in ITP patients and the associated risk is considered low. Possible risks of the venipuncture are formation of a small, local hematoma and pain/discomfort.

Patients are asked to come the UMC Utrecht for the venipuncture: travel expenses and parking costs will be compensated. The blood results that are relevant for the patient*s treatment will be sent to the patient*s physician, so the study withdrawals will be combined with the standard of care venipuncture.

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

- Age 16 years and older
- Previously confirmed diagnosis of primary ITP with current platelet counts of <100x10^9/L
- Will start treatment with eltrombopag
- Willing and be able to understand the study information and sign the informed consent form.

Exclusion criteria

- Documented history of persisting severe anemia (defined as hemoglobin <6.0 mmol/L for men and women)
- Treatment with rituximab in the past 9 months
- Treatment with any immune modulating drug other than corticosteroids in the past 3 months

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-12-2019
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	27-02-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	08-01-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-04-2021
Application type:	Amendment
Review commission:	METC NedMec

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	NL66840.041.18