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

No registrations found.

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

Summary

ID

NL-OMON28113

Source
Nationaal Trial Register

Brief title
I-ITP

Health condition

Immune thrombocytopenia (ITP)

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: Novartis Pharma B.V.

Intervention

Outcome measures

Primary outcome

Change in immunologic profile and platelet function before start and during treatment with eltrombopag

Secondary outcome

Difference in immunologic profile or platelet function at baseline between responding and non-responding patients

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 immune thrombocytopenia (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

Eltrombopag increases platelet activity and alters immune profiles in ITP

Study design

Before start of eltrombopag, and at 2-3 weeks, 3, 6 and 12 months

Contacts

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Eligibility criteria

Inclusion criteria

- Age 16 years and older
- Previously confirmed diagnosis of primary ITP with current platelet counts of <100x109/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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2019
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-05-2020
Application type:	First submission

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
NTR-new	NL8614
Other	METC UMCU : METC 18-859

Study results