Stop TPO-receptor agonist in ITP Patients

Published: 30-11-2016
Last updated: 15-05-2024

Find/confirm percentage of remission after discontinuing TPO-RA in persistent and chronic ITP patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Platelet disorders
Study type	Interventional

Summary

ID

NL-OMON54835

Source
ToetsingOnline

Brief title
STIP study

Condition

- Platelet disorders
- Autoimmune disorders

Synonym
immune trombocytopenia, ITP

Research involving
Human

Sponsors and support

Primary sponsor: Hagaziekenhuis
Source(s) of monetary or material Support: door de opdrachtgever (Hagaziekenhuis)

Intervention

Keyword: discontinuation/cessation, immune trombocytopenia, ITP, thrombopoietin receptor agonist

Outcome measures

Primary outcome

Primary outcome: Treatment success after 1 year of TPO-RA therapy. Success is durable response 4 weeks after tapering TPO-RA off at T3.

Secondary outcome

Secondary outcomes: Predictive value of 4 predictors defined in the figure above for successful tapering off. Remission rate after cessation TPO-RA at 12 months after cessation, QoL, Cost of drugs, Hospitalisation, Bleeding grade 3 or 4.

Study description

Background summary

According to the present guidelines, splenectomy is the therapy of first choice as second line therapy in primary immune thrombocytopenia (ITP). If splenectomy fails or patients have contraindications for splenectomy the guideline suggest the use of thrombopoietin receptor agonists (TPO-RAs). However, recently the label of the TPO-RAs has been changed, allowing the use of TPO-RAs in patients that have not been splenectomized and have no comtranindication for splenectomy. Therefore, TPO-RAs have become an alternative therapy for splenectomy in ITP patients.The major disadvantage of TPO-RAs is, they are considered to be symptomatic therapy and have to be given lifelong, resulting in a possible life-long chance of adverse events and a large impact on the medical budget. However, retrospective studies have shown that after discontinuation of TPO-RAs 26-55% of the subjects can achieve prolonged remission. A meta analysis of 99 studies (Zaja et al, 2020) shows an average remission rate of 40% in patients after tapering TPO-RA. To date no predictive values for the successful discontinuation of TPO-RAs are available. This study has been designed to confrim these numbers. Secondly, to find the value of predictieve tests as an aid for physicians in predicting successful discontinuation of TPO-RAs, if possible.

Study objective

Find/confirm percentage of remission after discontinuing TPO-RA in persistent and chronic ITP patients.

Study design

Single arm intervention prospective cohort study. Per protocol analysis.

Intervention

1 year TPO-RA use, then tapering off in 6 weeks.

Study burden and risks

Benefits: Possibly stopping medication for 30-40% of patients cost of drugs reduction, reduction of adverse events, lowest possible dose.
Risks: Risk of relapse in study, risk of relapse at tapering period (non-remission). Radiation from ITP-liver/spleen scan (1.56 mSv, considered not harmful). Extra blood samples will be acquired at the moment of regular blood sampling, thus no extra vena punctions are needed.
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Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Persistent or chronic ITP, 18 years old, in need of second line therapy after initial treatment with corticosteroids, informed consent

Exclusion criteria

Previous splenectomy, Bone marrow disease, Other bleeding disorder, Liver disease (Child Pugh above 7), Pregnancy, Secondary ITP, prior TPO-RA use (longer than 3 months of therapy)

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-07-2017
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	Nplate
Generic name:	romiplostim
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	30-11-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	19-12-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	06-06-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	09-06-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	04-06-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO
Date: 13-07-2018

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 30-11-2018

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 15-12-2019

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 06-08-2020

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 11-06-2021

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 05-06-2023

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22827
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2016-003810-29-NL
CCMO	NL58678.098.16
Other	Trial NL6605 (NTR6787)
OMON	NL-OMON22827