STIP study

Gepubliceerd: 17-10-2017 Laatst bijgewerkt: 15-05-2024

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22827

Bron
NTR

Verkorte titel
STIP

Aandoening

Chronic Immune Thrombocytopenia, ITP, TPO-RA, romiplostim, discontinuation

Ondersteuning

Primaire sponsor: Haga Teaching Hospital, The Hague
Overige ondersteuning: AMGEN

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Remission vs non-remission at 4 weeks after discontinuation of romiplostim treatment

Toelichting onderzoek

Achtergrond van het onderzoek

Thrombopoietin receptor agonists (TPO-RAs) are a second line treatment for chronic immune thrombocytopenia (ITP). A major disadvantage of TPO-RAs is they are considered symptomatic therapy and need to be prescribed lifelong with several associated adverse events. Furthermore, TPO-RA’s are expensive and have a large impact on the medical budget. Recent literature suggests between 26-52% of patients achieve prolonged remission of ITP after stopping TPO-RA. We aim to study the remission rate after safe discontinuation of TPO-RA treatment. Furthermore, we want to study if it is possible to predict remission success with patient characteristics, immunological markers and platelet sequestration patterns.

Doel van het onderzoek

Sustained remission after 1 year of TPO-RA treatment is about 15%. Secondly, we hypothesize change occurs during 1 year treatment with TPO-RA in auto-antibodies, T regulatory cells, TPO levels and/or ITP liver/spleen scan which might predict the success rate after cessation of TPO-RA.

Onderzoeksopzet

Baseline, 1-3 month, 6 monyhs, 1 year, 2 year.

Onderzoeksproduct en/of interventie

Tapering and discontinuation of romiplostim after 1 year.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Chronic primary ITP
- >18 years old
- Indication for second line treatment
- Informed Consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Splenectomy in history
- Secondary ITP
- Pregnancy or planning to become pregnant during the study period
- Hematologic/bone marrow/platelet disease in history or in co-existence
- Other bleeding disorder
- Liver disease (Child Pugh >7)
- Prior TPO-RA use

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	27-07-2017
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-10-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54835
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6605
NTR-old	NTR6787
CCMO	NL58678.098.16
OMON	NL-OMON54835

Resultaten