Thrombopoietin Receptor Agonist Patient experience survey

No registrations found.

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

Summary

ID

NL-OMON22426

Source
NTR

Brief title
TRAPeze

Health condition

Immune Thrombocytopenia

Sponsors and support

Primary sponsor: Sobi
Source(s) of monetary or material Support: Sobi

Intervention

Outcome measures

Primary outcome

The relative preferences towards TPO-RA product characteristics

Secondary outcome

Disease characteristics, patterns of treatment and satisfaction with therapy

Study description

Background summary

Real world evidence Burden of Illness cross-sectional study (discrete choice experiment and exploratory questions) to define patient preference towards existing TPO-RAs, to describe disease characteristics, patterns of treatment and satisfaction with therapy and to describe patient demographics, resource use, work and productivity and social impact.
Men or women ≥18 years of age; Formal diagnosis of primary ITP according to the ASH and ICR guidelines; Currently or have previously received a TPO-RA (either eltrombopag and/or romiplostim) in the last 12 months; Have been treated with a TPO-RA for a minimum of 3 months, with at least some of the treatment received in the last 12 months; Provide written informed consent; Ability to understand and respond in English; this does not need to be the participants' first language or even their own language if they wish to use their own translator. If recruitment appears to be limited by this, then translations of the survey will be made. Further plans for deployment will also see the survey translated into French, German, Italian and Spanish

Study objective

Participant demographics affect the health state.
TPO-RA treatment affects the severity of symptoms, overall health condition, health state, overall satisfaction with therapy and reasons for discontinuation.
TPO-RA treatment affects direct healthcare resource utilisation and costs.
TPO-RA treatment affects wider healthcare resource use and costs.

Study design

Primary endpoint (Participant preferences (or 'choice') towards TPO-RA product characteristics): discrete choice experiment through web platform, starting 1 August 2021 (pending ERC approval) and ending 31 December 2021. Participants have 1 week to fill out the online survey and are expected to need a total of 20 minutes for this.

Secondary endpoints (Participant demographics and disease characteristics, Patterns of treatment and overall satisfaction with therapy, Direct healthcare resource utilisation and costs & Wider social impact, healthcare resource use and costs): patient burden survey through web platform, starting 1 August 2021 (pending ERC approval) and ending 31 December 2021. Participants have 1 week to fill out the online survey and are expected to need a total of 10 minutes for this.

Intervention

N/A

Contacts

Public
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Scientific
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Eligibility criteria

Inclusion criteria

A subject must fulfill the following criteria in order to be included in the study:
1. Men or women ≥18 years of age
2. Formal diagnosis of primary ITP according to the ASH and ICR guidelines [14, 25]
3. Currently or have previously received a TPO-RA (either eltrombopag and/or romiplostim) in the last 12 months
4. Have been treated with a TPO-RA for a minimum of 3 months, with at least some of the treatment received in the last 12 months
5. Provide written informed consent
6. Ability to understand and respond in English; this does not need to be the participants' first language or even their own language if they wish to use their own translator. If recruitment appears to be limited by this, then translations of the survey will be made. Further plans for deployment will also see the survey translated into Dutch, French, German, Italian and Spanish

Exclusion criteria

The presence of any of the following will exclude a subject from inclusion in the study:
1. Known secondary immune thrombocytopenia
2. Foreseeable inability to cooperate with given instructions or study procedures
3. Inability to give consent

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):	01-08-2021
Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	17-06-2021
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	NL9571
Other	MEC-U : W21.145/ NWMO21.05.021

Study results