The Dutch ITP-registry, a national web-based tool for collection of diagnostic, therapeutical and evaluation data from patients with chronic immune trombocytopenic purpura.

No registrations found.

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

Summary

ID

NL-OMON21674

Source
Nationaal Trial Register

Brief title
STiC registry

Health condition

Number of patients treated. Effectivity, safety and cost-effectiveness of different treatment modalities, quality of life.

Sponsors and support

Primary sponsor: Dutch working party on non-malignant hematology of the Dutch Society of Hematology
Source(s) of monetary or material Support: Amgen, GSK, Roche

Intervention

Outcome measures

Primary outcome

1. How many patients need a treatment for chronic ITP;

2. Does the treatment work in non-selected patient group with chronic ITP;

3. What is the frequency and severity of side effects induced by new drugs in a non-selected patients group with chronic ITP;

4. What is the cost-effectiveness.

Secondary outcome

Quality of life.

Study description

Background summary

Immune thrombocytopenic purpura (ITP) is an immune-mediated acquired disease, characterized by a decreased platelet count and, depending upon the degree of thrombocytopenia, an increased risk of bleeding. A national guideline for the treatment of acute, persistent, and chronic ITP has been written by the Dutch working party on non-malignant hematology. However, treatment-related decisions still remain principally dependent on clinical expertise rather than clinical trial evidence. Introduction of new classes of therapeutic agents have enlarged the therapeutical arsenal even though the position of these agents is not completely clear.

With the ITP registry the knowledge of treatment and course of patients with chronic or persistent ITP is greatly improved. More Insight is obtained in the number of patients that need treatment, frequency and severity of side effects and cost-effectiveness.

Relevant data on every chronic ITP patient needing additional treatment (including wait-and-see patients, qualifying for ITP but not actively being treated but in follow-up) will be entered in the national web-based database. The working party on non-malignant haematology will ask all haematologists in the Netherlands to include their patients. Requests for use and study of aggregate data from the database are handled by the steering committee. The steering committee produces a yearly report of the status and use of the database, together with a summary of data.

Study objective

The mission of the chronic ITP registry is to improve the knowledge of the treatment and course of patients with persistent of chronic ITP. The objective of the registry is to get more insight in the number of patients that need a treatment for chronic ITP, what the effectivity, safety and cost-effectiveness is of the different treatment modalities in a non-selected patient population with chronic ITP. By collecting and analysing data, questions can be answered such as:

1. How many patients need a treatment for chronic ITP?

2. Does the treatment work in non-selected patient group with chronic ITP?

3. What is the frequency and severity of side effects induced by new drugs in a non-selected patients group with chronic ITP?

4. What is the cost-effectiveness?

5. What is the quality of life in respect to treatment?

Obviously, given the nature of the registry, only descriptive and non direct comparable results can be obtained.

Study design

Relevant patient data and QoL is entered in the national database twice a year after visitation treating physician.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

Adult patients (M/F) with chronic or persistent ITP (with history of splenectomy) needing additional treatment (inc. wait-and-see patients qualifying for ITP but not activily being treated but in follow-up).

Exclusion criteria

1. Minors;

2. Patients with acute or secundairy ITP.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2010
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-04-2010
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	NL2184
NTR-old	NTR2308
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A