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

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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…

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON21674

**Bron**
NTR

**Verkorte titel**
STiC registry

**Aandoening**

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

### Ondersteuning

**Primaire sponsor:** Dutch working party on non-malignant hematology of the Dutch Society of Hematology
**Overige ondersteuning:** Amgen, GSK, Roche

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

1. How many patients need a treatment for chronic ITP;<br>
2. Does the treatment work in non-selected patient group with chronic ITP;<br>
3. What is the frequency and severity of side effects induced by new drugs in a non-selected patients group with chronic ITP;<br>
4. What is the cost-effectiveness.

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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.

**Onderzoeksopzet**

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

**Onderzoeksproduct en/of interventie**

N/A

# Contactpersonen

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Minors;

2. Patients with acute or secundairy ITP.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-10-2010 |
| Aantal proefpersonen: | 300 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 28-04-2010 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL2184 |
| NTR-old | NTR2308 |
| Ander register | : |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**
N/A