Chronic disease in Immune Thrombocytopenia of Childhood

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

Summary

ID

NL-OMON36447

Source
ToetsingOnline

Brief title
The CIN-KID study: Chronic ITP in the Netherlands in Kids

Condition

- Platelet disorders
- Autoimmune disorders

Synonym
immune thrombocytopenic purpura, platelet destruction by antibodies

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: deels door Landsteiner Stichting;deels door nog aan te vragen fondsen

Intervention

Keyword: bleeding, chronic ITP, Quality of Life

Outcome measures

Primary outcome

The main study parameter is the correlation between platelet function parameters and clinical bleeding tendency in children with chronic ITP.

Secondary outcome

Secondary study parameters are 1) quantity and function of regulatory T cells in children with long lasting chronic ITP, 2) response to treatment(s) given in patients with chronic ITP and biological parameters that may be related to this response, 3) HR-QoL in children with chronic ITP and their parents.

Study description

Background summary

Newly diagnosed immune thrombocytopenia (ITP) in childhood is characterized by auto-immune destruction of platelets and a typical history of acute development of purpura and bruising in an otherwise healthy child. Most children with newly diagnosed ITP will recover within 6-12 months. However, 20-25% of the patients will remain thrombocytopenic and are diagnosed with chronic ITP, defined as a platelet count of less than 100 x 109/L for longer than 12 months.
Despite important progress in the understanding of ITP and the mechanisms of action of several therapeutic strategies in ITP, some clinical dilemmas can be recognized in both newly diagnosed and chronic ITP. These include 1) identification of patients at risk for severe bleeding, and 2) the inability to predict the disease course and the response to therapy in the individual patient at the time of diagnosis.
Although severe bleeding occurs only in about 2-3% of all patients with ITP, thrombocytopenia has a major influence on daily life activities. All activities which carry a risk of causing severe bleeding have to be avoided. Therefore, ITP has a significant impact on quality of life of children and their parents.

Study objective

The primary objective of this study is to identify parameters that predict bleeding risk in children with chronic ITP. Secondary objectives are: 1) To investigate whether children with long lasting chronic ITP differ from children with newly diagnosed ITP and adults with chronic ITP, with regard to quantity and function of regulatory T cells. 2) To determine the clinical and laboratory response to treatment(s) given in children with chronic ITP, and to identify biological parameters that determine this response and that possibly are involved in the differences in outcome between acute vs. chronic disease in childhood. 3) To measure the health related quality of life (HR-QoL) in children with chronic ITP and their parents.

Study design

This study comprises a multicenter prospective observational study

Study burden and risks

In this study, a history and physical examination will be performed in children with chronic ITP during a regular outpatient clinic visit. During blood sampling, an extra amount of 30 mL will be taken for study purposes. This amount is <0.1% of overall blood volume and therefore limited to such a degree that adverse consequences for patients are not to be expected. Finally, all parents, and from the age of seven years also the patients themselves, will be asked to fill out a questionnaire regarding the HR-QoL in chronic ITP.
ITP in children is a different disease than ITP in adults with regard to clinical course, response to therapy, as well as presumed etiology. The response to different kinds of treatment, especially immunomodulating treatment, also differs between children and adults with ITP. Therefore, to answer our questions, this study cannot be performed in an adult population.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Age 1-17 years
ITP lasting for more than 12 months
Visting a pediatric hematologist

Exclusion criteria

Clinical features that are not compatible with the diagnosis of chronic ITP, for example the presence of other autoimmune phenomena, other cytopenias besides thrombocytopenia (e.g. Hb< 6.0 mmol/l, leukocytes < 4.0 x 109/l), features susceptible for hereditary thrombocytopenia
No informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-05-2011
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	12-05-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL33740.041.10