Trombocytopathy in the Netherlands

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	-

Summary

ID

NL-OMON22771

Source
NTR

Brief title
TiN

Health condition

Platelet function disorders
Trombocytopathie

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

- Frequency and severity of bleeding symptoms: bleeding score using the ISTH-BAT

- Treatment of bleeding diathesis: type and frequency of treatment received in the past (local treatment, antifibrinolytics, DDAVP, platelet transfusion)

- Impact of PFD on quality of life: RAND-36 health survey score

Secondary outcome

- Diagnostic utility of additional platelet tests as compared to standard LTA

- Relation between type of PFD and bleeding phenotype

- Genotype-phenotype relationship

Study description

Background summary

A nationwide cross-sectional study of patients above 18 years of age with a (suspected) PFD will be performed. Frequency and severity of bleeding symptoms will be assessed using the ISTH bleeding assessment tool (BAT). Patients will complete a questionnaire on treatment history, social activities and quality of life, including items of the RAND-36 health survey. Blood will be drawn to perform routine laboratory testing for platelet function and additional tests, including the flow cytometry based Platelet ACtivation Test (PACT), MYH9 immunofluorescence analysis, mepacrine response, perfusion analysis, mass spectrometry and whole-exome sequencing (WES). Plasma will be stored in the biobank for additional testing in the future. This study combines clinical burden, functional assays, WES and mass spectrometry, generating a unique platform to better understand PFD’s and to improve patient care.

Study objective

Observational study to register and investigate patients in the Netherlands with a (suspected) PFD, to assess clinical presentation, bleeding score, burden of disease and quality of life.

Study design

None

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

- Age > 18 years

- History of bleeding diathesis suspected for a PFD

Exclusion criteria

- Inability to give informed consent

- Bleeding diathesis due to an acquired PFD, von Willebrand disease, hemophilia or other disorders of secondary hemostasis or fibrinolysis

- Current use of antiplatelet therapy

Study design

Design

Intervention model: Other

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-02-2016
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-08-2016
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	NL5878
NTR-old	NTR6051
Other	NL53207.041.15 : 15-597

Study results