Thrombosis and paroxysmal nocturnal hemoglobinuria clones

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The goal is to investigate wether a PNH clone could be the cause of an unexplained thrombosis. In the population of patients with unexplained thrombosis a PNH clone may be the cause.The goal is to investigate whether the prevalence of PNH clones is...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Embolism and thrombosis
Study type	Observational invasive

Summary

ID

NL-OMON43444

Source
ToetsingOnline

Brief title
Thrombosis and PNH clones

Condition

- Embolism and thrombosis

Synonym
Paroxysmal Nocturnal Hemoglobinuria/Paroxysmal nocturnal red urine

Research involving
Human

Sponsors and support

Primary sponsor: Scheper Ziekenhuis
Source(s) of monetary or material Support: Alexion Pharmaceuticals,Bedrijf en eigen ziekenhuis

Intervention

Keyword: PNH, Thrombosis

Outcome measures

Primary outcome

To determine the prevalence of PNH clones within the selected population .

Secondary outcome

Not applicable

Study description

Background summary

Paroxysmal nocturnal hemoglobinuria (PNH) is an acquired genetic disorder of the hematopoietic stem cell. The disorder is characterized by intravascular hemolysis with hemoglobinuria and thrombosis which can be life threatening. Several studies have shown that approximately 1.4 % of patients with venous or arterial thrombosis with unexplained cause have a PNH clone. This PNH clone may have been the cause of a first thrombotic event.
The clinical chemistry laboratory of the Treant Zorggroep location Scheper has the possibility to detect small PNH clones by flow cytometry.

Study objective

The goal is to investigate wether a PNH clone could be the cause of an unexplained thrombosis. In the population of patients with unexplained thrombosis a PNH clone may be the cause.

The goal is to investigate whether the prevalence of PNH clones is described correctly in literature.

Study design

All patients with unknown cause of thrombosis from the patients database of the thrombosis service from Treant zorggroep, hospital location Scheper will be selected.
After obtaining written consent, one extra tube of blood (4 mL) is collected during a regular venapuncture. In this blood sample, the presence or absence of a PNH clone is determined.

Name and address data, date of birth, diagnosis and the outcome of the investigation is stored encrypted for all patients.
There is no control group.
The investigation relates to disease(s) from the classes vascular disorders.
The planned start date is September 1, 2016. The estimated completion date is June 30, 2016 .

Study burden and risks

One extra tube of blood will be withdrawn during regular blood sampling. The burden is therefore nihil. The risk of a venapuncture is negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Deep Vein Thrombosis
Recidive Deep Vein Thrombosis
Mesenterial Thrombosis
Pulmonary Embolism

Exclusion criteria

< 18 y and > 80 y
Incompetent
Known Cause of Thrombosis/Embolism

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2016
Enrollment:	325
Type:	Actual

Ethics review

Approved WMO

Date:	05-07-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL56506.042.16