Characterisation of auto-antibodies against ADAMTS-13 in patients with a history of TTP.

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

Summary

ID

NL-OMON32888

Source
ToetsingOnline

Brief title
ADAMTS-13 in TTP

Condition

- Embolism and thrombosis

Synonym
small vessel thrombosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ADAMTS-13, Thrombosis, TTP

Outcome measures

Primary outcome

The anti ADAMTS-13 antibodies epitopes in patients with a history of TTP

Secondary outcome

Not applicable

Study description

Background summary

Thrombotic thrombocytopenic purpura (TTP) is a rare and potentially life-threatening auto-immune disorder, characterised by multiple micro-angiopathic thrombosis, haemolytic anemia and ischemic organ dysfunction. In the past years, it has become clear that a deficiency of a von Willebrand factor cleaving protein, a desintegrin and metalloproteinase with thrombospondin type 1 motif (ADAMTS-13), is at the basis of the pathogenesis of TTP (1). It results in the presence of ultralarge molecular weight multimers of von Willebrand factor (2), which in turn leads to a pro-thrombotic stage where thrombocyt aggregation is enhanced and microthrombi are formed.

The deficiency of ADAMTS-13 in acquired TTP is thought to be an auto-immune process: immunoglobulin G antibodies directed against ADAMTS-13 can be found in all patients with acute TTP. All antibodies are directed against the spacer domain in ADAMTS-13.

In the current proposal we will investigate the pattern of auto-antibodies in patients with a history of TTP. It is known that in 50% of these cases ADAMTS-13 is absent, without any sign of TTP. We hypothesize that antibosies in this chronic phase are present but directed against other epitopes.

Study objective

Characterisation of auto-antibodies against ADAMTS-13 in patients with a history of TTP

Study design

Patients will be asked to participate by the Dutch TTP "patiëntenvereniging". During the yearly contact day ex-TTP patients will be asked to donate 20 ml of blood and to fill in a short questionaire. It is a cross-sectional study and 50 patients will be included in the following 5 years.

Study burden and risks

venapunction (20 ml)

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

Patients with a history of TTP

Exclusion criteria

<18 years

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2008
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	04-11-2008
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	NL23996.041.08