ADAMTS-13 levels in patients with a history of thrombotic thrombocytopenic purpura.

Published: 24-10-2006
Last updated: 09-05-2024

Purpose: Determine the ADAMTS-13 activity in patients with a history of TTP.

Ethical review	Not approved
Status	Will not start
Health condition type	Haematological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON29947

Source
ToetsingOnline

Brief title
ADAMTS-13 levels in TTP patients.

Condition

- Haematological disorders NEC

Synonym
thrombotische thrombocytopenic purpura

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ADAMTS-13, TTP

Outcome measures

Primary outcome

End point: determination of the ADAMTS-13 activity in blood and the relation

with relapsing TTP.

Secondary outcome

not applicable

Study description

Background summary

ADAMTS-13 is involved in the life treatening clottingsdisease TTP. The protein ADAMTS-13 facilitates the break down of von Willebrand factor. When the protein is prefented by antibodies to break down the vWF thrombosis can occur. TTP is treated with plasmaexchange. If TTP is discovered in time it can be treated well. Recently is discoverd that patients with a history of TTP that have no ADAMTS-13 activity also have less ADAMTS-13 activity on the long term. Possibly a small amount of ADAMTS-13 activity is enough to prevent a TTP episode, though low amounts of ADAMTS-13 activity can cause complaints. Moreover low amounts of ADAMTS-13 activity is a possible riskfactor for new relapses of TTP.

Study objective

Purpose: Determine the ADAMTS-13 activity in patients with a history of TTP.

Study design

Study design: Cross-sectional and prospective study
Starting: 01-09-2006, ending: 01-09-2016

50 TTP patients (m/f) with a history of TTP are approached by the TTP patient association to visit the annual patient day. During this day patients are asked to fill in a questionnaire and give permission to donate blood for scientific research (cross-sectional part). Blood will be drawn during this day at the

UMCU. The patient day will be held annually, and every time permission will be asked for blood withdrawal and filling in the questionnaire (prospective part). In the future we would like to investigate the relation between relapsing TTP and the presence or absence of Adamts-13 with this study design .

Study burden and risks

Participation is of hardly any burden. Patients are asked to fill in a questionnaire on the history and course of their TTP episodes. After consent 10 ml blood is withdrawn by qualified personnel for scienentific research. Risk: hematoma after venipuncture

Het onderzoek is nauwelijks belastend. De patiënten worden gevraagd een enquete in te vullen over het verloop en voorgeschiedenis van de TTP aanval. Na het verkrijgen van toestemming wordt 10 ml bloed afgenomen door gekwalificeerd personeel voor wetenschappelijk onderzoek. Risico: hematoom na venapunktie.

Contacts

Public
Academisch Medisch Centrum

Heidelberglaan 100
3584 CX Utrecht
Nederland
Scientific
Academisch Medisch Centrum

Heidelberglaan 100
3584 CX Utrecht
Nederland

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 thrombotic thrombocytopenic purpura. Patients are approched by the

Exclusion criteria

None

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Ethics review

Not approved

Date:	24-10-2006
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	NL13794.041.06