

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

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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-OMON30494

Source

ToetsingOnline

Brief title

ADAMTS-13 levels in TTP patients

Condition

- Haematological disorders NEC

Synonym

thrombotic 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 threatening disease 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 plasmachange. If TTP is discovered in time, it can be treated well. Recently it was discovered that patiens with a history of TTP that have no ADAMTS-13 activity, also have less ADAMTS-13 activity on the lon term. Possibly a small amount of ADAMTS-13 activity is enough to prevent a TTP episode, though low amounts of ADAMTTS-13 can cause complaints. Moreover, low amounts of ADAMTS-13 activity is a possible risk factor for new relapses of TTP.

Study objective

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

Study design

50 TTP patients (m/f) with a history of TTP are approached by the TTP patient association to visit the annual patient day. The patients are asked to fill in a questionnaire and give permission to donate blood for scientific research. (cross-section). Blood will be drawn during this day at the UMC Utrecht. The patient day will be held annually, and every time permission will be asked for blood withdrawl and filling in the questionnaire (prospective part). In the future we would like to investigate the relation between 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 disease and after consent 10 ml blood is withdrawn by qualified personnel for scientific research. Risk: hematoma after venipuncture.

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 thrombotic thrombocytopenic purpura. Patients are approached by

the patient association.

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: 06-03-2007

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

CCMO

ID

NL15965.041.07