D-dimer and Factor XIII activation peptide in cerebral venous thrombosis (CVT)

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To assess the sensitivity and negative predictive values of D-dimer- and FXIII activation peptide (AP-FXIII) values in order to exclude to exclude CVT in patients with clinical suspicion of CVT.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON43567

Source
ToetsingOnline

Brief title
D-dimer and AP-FXIII in CVT

Condition

- Central nervous system vascular disorders

Synonym
Cerebral Venous Sinus Thrombosis(CVST), Cerebral Venous Thrombosis(CVT), Sinus thrombosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cerebral Venous Thrombosis (CVT), D-dimer, Diagnosis, Factor XIII activation peptide

Outcome measures

Primary outcome

Plasma D-dimer and AP-FXIII levels analyzed according to newly developed highly

sensitive and specific ELISA methods in patients with CVT and only suspicion of

CVT.

Secondary outcome

-overall frequency of CVT in patients with clinical suspicion of CVT

-overall frequency of other diseases in patients with clinical suspicion of CVT

-site of involved veins and sinus in patients with CVT

Study description

Background summary

Cerebral venous and sinus thrombosis (CVT) is a relatively uncommon form of stroke. The clinical spectrum of CVT can be extremely diverse which makes diagnosis of CVT a challenging job for physicians. CT-venography or MR-venography are costly, not always available on a emergency basis, time-consuming and, in the case of CT-V, submit the patient to a significant level of radiation. A simpler test to exclude CVT like D-dimer concentration and/or the newly investigated FXIII activation peptide (AP-FXIII) concentration would be welcome. However, the diagnostic value of these tests are still under debate and further research is required.

Study objective

To assess the sensitivity and negative predictive values of D-dimer- and FXIII activation peptide (AP-FXIII) values in order to exclude to exclude CVT in patients with clinical suspicion of CVT.

Study design

Observational prospective multi-centre cohort study. Consecutive patients with clinical suspicion of CVT will be included in this study over a two year period. All included patients will receive standard care applied by the treating physician who will follow international recommendations. Participation in the study has no influence on treatment decision. On admission patients will undergo a standard diagnostic work-up, including a clinical neurological examination, routine laboratory examination and brain CT-venography or MRI/MRV. For the study D-dimer values and plasma AP- FXIII will be analyzed at the Hemostasis Research Laboratory, Department of Hematology, AMC according to a newly developed highly sensitive and specific ELISA method. The laboratory technician will be blinded for the clinical symptoms and diagnosis of the patient. The study will be conducted according to the guidelines of the STARD (Standards for Reporting Diagnostic Accuracy) initiative.

Study burden and risks

There are no personal benefits for participating subjects. Their participation may help patients in the future suspected of CVT. Aside from the inconvenience of undergoing a venapunction, there are no risks associated with participation in this study.

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

Any adult patient with a clinical suspicion of CVT where the treating neurologist considers radiological investigation (CT-V or MR-V) to be required

Exclusion criteria

none

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):	01-01-2012
Enrollment:	520
Type:	Actual

Ethics review

Approved WMO Date:	18-11-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT00924859
CCMO	NL37679.018.11