The calibrated automated thrombogram as a clinical test for monitoring hypercoagulability in patients with cerebral venous sinus thrombosis.

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Is it possible to detect prothrombotic states via the "calibrated automated thrombogram" in patients that endured CVST, who did no show deviations in the prothrombin time/activated partial thromboplastin time? Secondary, we will...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational invasive

Summary

ID

NL-OMON46638

Source
ToetsingOnline

Brief title
CVST-study

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Embolism and thrombosis

Synonym
venous sinus thrombosis, venous stroke

Research involving
Human

Sponsors and support

Primary sponsor: Laboratory for Clinical Thrombosis and Haemostasis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Calibrated automated thrombogram, Cerebral venous sinus thrombosis, Hemostasis, Thrombingeneration

Outcome measures

Primary outcome

Primary outcomes of the calibrated automated thrombogram are: lag time, time to peak, peak height, endogenous thrombin potential (area under the curve) and peak reduction.

Secondary outcome

In addition, determinants which influence the coagulation cascade will be measured (i.e.: PT, aPTT, Thrombintime, Fibrinogen, Prothrombin, Anti-thrombin, Free tissue factor pathway inhibitor (TFPI), TFPI activity, Protein C, Free Protein S, Total Protein S, vWF activity, vWF antigen, FVIII activity, FVIII antigen, FV activity, FVII activity, FXI activity, FX activity, FXI activity, FXII activity, FXIII activity, a2-antiplasmin, PAI-1 activity).

Study description

Background summary

The haemostatic thrombotic system (HTS) is a very diverse and complex system, in which thrombin is the key player. One of the conditions in which the HTS is altered, is cerebral venous sinus thrombosis (CVST); a relatively rare, but potentially lethal condition. In approximately 15 per cent of these patients, the cause of CVST remains unclear. Conventional clotting tests, such as prothrombotic time and activated partial thromboplastin time, analyse the most

common aberrant factors of the coagulation cascade. Within these tests, it is not possible to detect prothrombotic conditions nor to detect mild haemostatic abnormalities. Therefore, there is need for a physiological function test that can detect even minor aberrations. The calibrated automated thrombogram (CAT) assay is a test which measures the process of thrombin generation as a whole via fluorescence. By investigating the coagulation cascade in this manner, it might be possible to detect even mild haemostatic disorders as well as the prothrombotic state. This enables us to monitor patients with CVST who did not show any aberration(s) in conventional clotting tests.

Study objective

Is it possible to detect prothrombotic states via the "calibrated automated thrombogram" in patients that endured CVST, who did no show deviations in the prothrombin time/activated partial thromboplastin time? Secondary, we will investigate which molecular determinants of the thrombin generation curve are affected in patients with CVST.

Study design

Pilot patient-study

Study burden and risks

Burden and risk associated with participation: All eligible subjects have to make an appointment for antecubital venipuncture and to fill in the questionnaire. The total research time is 30 minutes for one subject. The risks for participants are small.
Benefit: Subjects do not directly benefit from positive results of the study.
Group relatedness: Group selection is based on the population of patients admitted to Maastricht University Medical Centre (MUMC), who endured CVST in the past three years. For both the study group as the control group no other base population can be used.

Contacts

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Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion criteria patient group:
Age above 18 years
Male and female
Radiologically proven sinus thrombosis in the past 3 years;Inclusion criteria control group:
*Inclusion criteria control group
Age above 18 years
Male and female

Exclusion criteria

Exclusion criteria patient group:
Patients with known coagulation disorders
Patients with a malignancy
Patients on hormonal contraception or who receive other hormonal therapy
Current use of oral anticoagulants
Incapacitated/ mentally disabled subjects;Exclusion criteria control group:
Known coagulation disorders
Subjects with known malignancy
Use of oral hormonal contraception or other hormonal therapy
Current use of oral anticoagulants
Incapacitated/disabled subjects*

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-05-2018
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	08-03-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL63775.068.17