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

Published: 08-03-2018 Last updated: 12-04-2024

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

**Public** Selecteer

Universiteitssingel 50 Maastricht 6229ER NL **Scientific** 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
Туре:	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

ССМО

**ID** NL63775.068.17