Cross-sectional study on plasma levels of activated protein C and related plasma proteins in Factor V Leiden and Prothrombin Mutation carriers

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The primary objective is to determine whether APC is elevated in thrombophilia carriers compared to non-carriers. In parallel we will address. Secondary objectives include assessing whether biomarkers related to angiogenic pathways downstream of APC...

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

Summary

ID

NL-OMON42226

Source
ToetsingOnline

Brief title
APC thrombophilia study

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
mutations that increase the risk of blood clots, Prothrombotic mutations

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: NWO

Intervention

Keyword: Activated protein C, Factor V Leiden, Prothrombin mutation, Thrombophilia

Outcome measures

Primary outcome

Plasma levels of APC and related plasma proteins.

Secondary outcome

Plasma levels of proteins related to angiogenic pathways. The correlation

between the APC plasma levels according to conventional and the novel assay.

Study description

Background summary

Heritable thrombophilia likely leads to elevated levels of activated protein C (APC) through enhanced thrombin formation, but earlier studies are inconsistent. APC elevation can possibly explain some of the non-coagulation related phenotypes seen in heritable thrombophilia through APC*s interactions with various pathways. Pathways that can be influenced by APC include the EPCR and PAR1 signaling pathway, the Tie2/Angiopoietin system and the plasminogen/plasmin system. We hypothesize that these pathways might be involved in creating the favorable phenotypes of thrombophilia mutation carriers seen in fertility, pregnancy complications, diabetic nephropathy, sepsis and acute respiratory distress syndrome.

Study objective

The primary objective is to determine whether APC is elevated in thrombophilia carriers compared to non-carriers. In parallel we will address. Secondary objectives include assessing whether biomarkers related to angiogenic pathways downstream of APC are altered in thrombophilia carriers compared to non-carriers and evaluating a novel APC assay compared to a conventional one.

Study design

Cross-sectional study.

Study burden and risks

Subjects will be undergo a single venipuncture during one visit. The risk and burden are considered low. Participation has no benefit to the individual subject.

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

Population 1: healthy, 18 years or older, thrombophilia carriership (cases).
Population 2: healthy, 18 years or older, pregnant, thrombophilia carriership (cases)

Exclusion criteria

Medication that influences secondary hemostasis, known risk factors for venous thromboembolism, current pregnancy complications.

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-04-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	24-02-2015
Application type:	First submission
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
CCMO	NL51349.018.14