Genetic factors, serum markers, and the risk of TIA and stroke.
Collection and storage of peripheral blood samples for neurovascular research in the Rotterdam Stroke Databank

Published: 12-06-2007
Last updated: 08-05-2024

To identify novel risk factors for TIA and stroke that can be measured in peripheral blood samples, in particular levels of proteins and other markers and genetic polymorphisms.

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

Summary

ID

NL-OMON30779

Source
ToetsingOnline

Brief title
Genetic and serum factors and risk of neurovascular events.

Condition

- Central nervous system vascular disorders

Synonym
cerebral infarct / hemorrhage, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: DNA, risk factors, Stroke, TIA

Outcome measures

Primary outcome

The study is primarily aimed at the collection and storage of blood samples and questionnaire data for future scientific research. The exact content of this study is at this moment only partially specified. We aim to answer the following research questions:

1) Are (genetic) factors that play a role in blood coagulation (hemostasis) associated with the risk of TIA or stroke in this clinical cohort?
With more specific sub-questions:
-are levels of fibrinogen and fibrinogen-degradation products associated with the risk of the outcome-measures under study?
- are variations in the fibrinogen-FGA en FGG genes associated with the risk of the outcome-measures under study?
-are other genetic variations that play a role in hemostasis associated with the risk of the outcome-measures under study?

2) Are new genetic risk factors for atherosclerosis associated with the risk of TIA or stroke in this clinical cohort?

With more specific sub-questions:

-are variations in the alpha-adducin gene (ADD1) associated with the risk of

the outcome-measures under study?

-are genetic polymorphisms that play a role in metabolism of homocysteine (an

established risk factor for atherosclerosis and stroke) associated with the

risk of the outcome-measures under study?

-are other genetic variations that influence risk factors for atherosclerosis

associated with the risk of the outcome-measures under study?

3) Can results from a genome-wide association study, aimed at identifying new

risk genes for TIA or stroke, be replicated in this clinical cohort?

Secondary outcome

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Study description

Background summary

Although several risk factors for transient ischemic attacks (TIAs) and stroke have been identified, in a substantial proportion of TIAs and strokes the exact cause remains unknown, even after ancillary investigations. Further studies are required to identify additional risk factors , in order to improve prevention and treatment of these neurovascualr events.
Furthermore, there is a need for predictive variables that can be measured in an easy, inexpensive, and minimally invasive way, to enhance their usefulness and applicability in daily clinical practice.
Peripheral bood samples are easily obtained through a minimally invasive routine procedure, and can yield a large amount of information, including on genetic factors.
In recent years, scientific interest has grown in the role of genetic factors

and gene-environment interactions in the pathogenesis of TIA and stroke. Studying genetic polymorphisms and gene-environment interactions in relation to occurrence of stroke or TIA may enhance insight in the pathogenetic mechanisms that ultimately lead to vascular events.

Study objective

To identify novel risk factors for TIA and stroke that can be measured in peripheral blood samples, in particular levels of proteins and other markers and genetic polymorphisms.

Study design

Case-control design. Data (levels of serum markers and genetic polymorphisms) will be collected of patients and control persons and compared through logistic regression, with adjustment for potential confounders (obtained through a questionnaire or from routine discharge letters). Multiplicative interactionterms will be added to the statistical model to evaluate gene-environment interactions.

Study burden and risks

The burden associated with participation in the study will consist of a single venapunction, involving withdrawal of 20 ml of blood. Control persons will also be asked to complete a short questionnaire. No risks are involved in 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

Patients:
1) Acute stroke treated in the Stroke Unit of the department of Neurology
2) Transient ischemic attack (TIA) or minor ischemic stroke at the outpatient TIA service
3) Patient should be able to give informed consent
Control persons:
Spouses, partners, friends or neighbours of patients who are included in the current study, without a history of ischemic or hemorrhagic stroke or TIA.

Exclusion criteria

Relatives of patients do not qualify for control persons (because future research will include the study of genetic polymorphisms).
Persons who are not able to give informed consent will not be included in the study.

Study design

Design

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

Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2007
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	12-06-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL16323.078.07