Circulating Nanotraces to Identify the Cause of Stroke

Published: 11-09-2020 Last updated: 15-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON52758

Source ToetsingOnline

Brief title CINTICS

Condition

- Neurological disorders NEC
- Vascular disorders NEC

Synonym

cerebrovascular accident, stroke

Research involving Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum **Source(s) of monetary or material Support:** De Hartstichting (2018B031),Exometry BV,Lionix International,Nico.lab

Intervention

Keyword: biomarker, extracellular vesicles, hermorrhagic strkoe, ischemic stroke

Outcome measures

Primary outcome

The collected blood will be analysed on the presence of differentiating markers, in this case EV concentrations, that can be related to different causes of stroke.

It will be examined whether ischemic strokes can be differentiated from

hemorrhagic strokes and stroke mimics. Moreover, in the ischemic stroke group

it will be examined whether small vessel occlusions can be discriminated from

large-vessel occlusions.

Secondary outcome

Secondary, relations between the EV concentration(s) and other clinical and

radiological findings than the diagnosis will be explored.

Study description

Background summary

In the Western world, stroke is the most frequent cause of major diability and the third cause of death. Half of the stroke survivors need life-long medical support. The causes of stroke can be subdivided into hemorrhagic stroke (ruptured artery) or an ischemic stroke (blocked artery). These different subtypes of stroke need different acute treatment approaches. The 'Time is brain' principle is thereby crucial, because 2 million brain cells die per minute in an acute stroke. Currently, a CT-scan made in the nearest hospital determines the exact cause of stroke, which is used to decide whether the patient needs further transport to a comprehensive stroke center, thereby losing precious time.

We hypothesize that there are blood markers that could be used to diagnose the

cause of stroke.

Study objective

The aim is to develop a method that can be used to determine, already in the ambulance, whether a patient suffers a stroke and if so, what the cause of stroke is. In this project we want to develop nanotechnology that is capable of detecting nanotraces within the blood. If successful, this would contribute to the improvent of current diagnostics.

The composition and concentration of extracellular vesicles (EVs) in blood will be determined and it will be examined which EVs might differentiate between ischemic and hemorrhagic stroke. Moreover, it will be examined whether differences can be found between the EV concentration of small- and large vessel occlusions. It is also of interest whether the concentrations of EVs is related to the location of stroke.

Study design

This concerns a multicenter observational study.

Study burden and risks

The burden and risks associated with participation are considered low. In this study, extra blood will be collected once (10 mL maximal), simultaneously with the regular blood collection. The risks associated with a venepuncture are considered negligible.

Despite the study population consists of (possibly) incapacitated patients (due to brain damage caused by the stroke), the researchers consider the burden and risks justified. This study cannot be done with patient groups different than the one described.

Contacts

Public Academisch Medisch Centrum

Meibergdreef 9 Amsterdam 1105AZ NL Scientific Academisch Medisch Centrum Meibergdreef 9 Amsterdam 1105AZ NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age 18 years or older
- Presenting with symptoms suggestive of stroke
- Written informed consent (deferred)

Exclusion criteria

Untreated coagulation abnormalities Specific stroke treatment has started before study blood has been collected

Study design

Design

Study type: Observational invasiveMasking:Open (masking not used)Control:UncontrolledPrimary purpose:Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	16-10-2020
Enrollment:	750
Туре:	Actual

Ethics review

Approved WMO	
Date:	11-09-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	29-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	13-05-2022
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

ID: 27763 Source: NTR Title:

In other registers

Register	ID
ССМО	NL72929.018.20
OMON	NL-OMON27763

Study results

Date completed:	31-10-2022
Actual enrolment:	479