Cohort study ON Neuroimaging, Etiology and Cognitive consequences of Transient neurological attacks (CONNECT)

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The overall objective of this study is to assess to what extend different cognitive domains are affected by a recent TNA and which mechanism is responsible for this cognitive decline. We wanted to know whether the kind of TNA (focal, non-focal,...

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

Summary

ID

NL-OMON34797

Source
ToetsingOnline

Brief title
CONNECT

Condition

- Central nervous system vascular disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
minor stroke, TIA, warning stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Hersenstichting Nederland

Intervention

Keyword: Cognition, Etiology, Imaging, Transient Ischemic Attack (TIA)

Outcome measures

Primary outcome

• Neuropsychological test results

• Lesions on conventional brain MRI compatible with cerebral ischemia.

• Lesions on advanced brain MRI compatible with diminished structural or

functional connectivity of brain networks.

Secondary outcome

Potential causes of mixed and non-focal TNA.

Study description

Background summary

Transient Neurological Attacks (TNAs) are transient neurological signs with acute onset. These TNAs are common among elderly people. The signs and symptoms may be focal, like hemiparesis, or non-focal, like acute cognitive complains. The focal TNAs have an ischemic cause and are therefore referred to as Transient Ischemic Attacks (TIAs). The cause of non-focal TNAs is unknown. Recently an increased risk of dementia was found among people with non-focal TNAs. We know that silent brain infarcts are also common among elderly people and that these lesions can eventually result in dementia, in particularly if they are located in eloquent brain areas.
This study should answer the question whether cognitive function declines after a TNA and whether this decline depends on 1) the kind of TNA (focal or non-focal) and 2) the presence and incidence of silent brain infarcts on MRI. Subsequently we aim to study cognitive decline in this population with advanced MR techniques to assess whether structural and functional connectivity of neuronal networks in the brain are involved in cognitive decline after a TNA.

Study objective

The overall objective of this study is to assess to what extend different

cognitive domains are affected by a recent TNA and which mechanism is responsible for this cognitive decline. We wanted to know whether the kind of TNA (focal, non-focal, mixed), presence of vascular risk factors, lesions seen on conventional MRI, like silent brain infarcts, white matter lesions and atrophy (in part) determine the risk of cognitive decline. Subsequently we aim to study the role of structural and functional connectivity of brain networks in cognitive decline in this particular patient population. Finally we want to study the causes of non-focal and mixed TNAs.

Study design

This is an observational study with a prospective cohort design.

Study burden and risks

Non contrast enhanced MRI has no known additional risk in patients without contraindications for MRI (like pacemakers).As part of regular patient care all potential participants in the study already had one MRI as part of their clinical work-up. Therefore chance findings (like menigeoma) are unlikely in this study. Part of the neuropsychological tests are part of regular patient care. Additional tests in non-demented people are supposed not to be very aggravating. Currently these tests are used in ongoing large population based cohort studies.

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

Recent Transient Neurological Attack

Exclusion criteria

history of ischemic or hemorrhagic stroke and dementia

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2011
Enrollment:	192
Type:	Actual

Ethics review

Approved WMO Date:	22-10-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-05-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-08-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL31651.091.10