Observational Dutch Young Symptomatic StrokE studY - Extended

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To investigate the role of the immune system in the etiology and prognosis in an acute ischemic stroke (or TIA) in young stroke patients.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON54052

Source
ToetsingOnline

Brief title
ODYSSEY nEXT

Condition

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

Synonym
cerebrovascular accident, Stroke

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cardiovascular disease, Immune system, Prognosis, young Stroke

Outcome measures

Primary outcome

What is the role of the immune system in the cause of a first-ever ischemic stroke or TIA before their 50th year?

Secondary outcome

• What is the role of triggerfactors on the immune system in patients with a first-ever ischemic stroke or TIA before their 50th year?

• What is the role of the immune system on the vascular wall function in patients with a first-ever ischemic stroke or TIA before their 50th year?

• What is the risk of long term complications in patients who suffer from an ischemic stroke or TIA between their 18th and 50th year?

• What is the impact of a first-ever ischemic stroke or TIA before their 50th year on the functional prognosis?

• What is the effect of coping strategies on cognitive and functional prognosis in patients with a first-ever ischemic stroke or TIA before their 50th year?

Study description

Background summary

Yearly, approximately 1200 young adults have a stroke in the Netherlands. In contrast to the older stroke population, a lot remains unknown regarding the etiology, secondary prevention and especially the long-term prognosis for these "young stroke" patients. In the elderly, cardiac problems and atherosclerosis are the main causes of stroke. However, these causes are much less frequent in the young. In around 20% of young patients the stroke is caused by a

heterogeneous group of rare diseases and in even 30-40% the cause of stroke remains completely unknown.
These different etiologies or even unknown etiology combined with a longer life-expectancy in these young adults compared to the older patients, means that study results on prognosis and secondary prevention cannot just be extrapolated from trials and studies in the elderly stroke population.

Based on our own young stroke studies, we observed that so called triggerfactors such as a fever or inflammation days before a stroke might play a role in etiology. This suggest that an interaction between inflammation and coagulation (the immune system) might lead to a stroke in vulnerable individuals. That is why we want to investigate the role of the immune system in the development of a stroke at young age. Additionally, studies suggest that patients with a disruptive immune system after a stroke have worse functional prognosis. However, studies about the long term effects of a disruptive immune system in young stroke patients are not known.

Study objective

To investigate the role of the immune system in the etiology and prognosis in an acute ischemic stroke (or TIA) in young stroke patients.

Study design

Multi-center prospective cohort study

Study burden and risks

Blood will be collected from patients twice and patient will undergo an 3T MRI once. Additionally, we have questionnaires (online/via telephone) which contain questions about triggerfactors, incidence cardiovascular events, post-stroke epiplepsy, medication use, daily and social functioning, coping and subjective cognition.

There are no big risks regarding the 3T MRI in patients without contraindication and can be safely performed. Some patients experience some discomfort due to the MRI. Patients will be provided with air protection for the sound and protection of the ear. Additionally, we try to reduce discomfort for the patients by providing pillows when laying down. Patients can always stop the MRI scan at every random moment. There is a small risk of bruising, bleeding or infection by positioning an infusion line or an allergic reaction to the Gadovist contrast.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patients with a first-ever transient ischemic attack (TIA) or acute ischemic stroke aged between 18 and 50 years old will be included. For this study, acute stroke is defined as "occurence of acute neurological deficit lasting more than 24 hours, with confirmation on imaging (CT(-a) or MR(-a))".TIA is defined as "occurence of acute neurological deficit lasting less than 24 hours with confirmation of ischemia on MRI). Patients are able to provide informed consent and a kidney function eGFR>30ml/min.

Exclusion criteria

Main exclusion criteria are: history of clinical TIA, ischemic stroke or intracerebral hemorrhage. A intracerebral hemorrhage resulting from trauma,

known aneurysm or underlying intracerebral malignancy. A venous infarction, retinal infarction and amourosis fugax. Inadequate control of the Dutch language to reliably sign an informed consent from and/or participate in the follow-up. Patients are excluded if they have a contra indication for 3T MRI.

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:	Recruiting
Start date (anticipated):	06-02-2023
Enrollment:	260
Type:	Actual

Ethics review

Approved WMO Date:	07-06-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-11-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-05-2023
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-04-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-09-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-09-2024
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	NL77518.091.21