The temporal cellular landscape of the adaptive immune system in patients with acute stroke

Published: 22-12-2020
Last updated: 30-11-2024

1. To either confirm or refute the hypothesis that a subset of brain regulatory T cells exists in humans and expands after stroke.2. To identify immunological biomarkers that can be used in stroke clinical trials targeting the adaptive immune system...

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

Summary

ID

NL-OMON50947

Source
ToetsingOnline

Brief title
TAPAS

Condition

- Central nervous system vascular disorders

Synonym
brain infarction, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Hoffmann-La Roche,Roche

Intervention

Keyword: Immunology, Stroke

Outcome measures

Primary outcome

We will assess the amount and characteristics of regulatory T cells in peripheral blood, lymph nodes and different brain areas of stroke patients and compare these with patients without stroke.

Secondary outcome

To determine the immune temporal cellular landscape of the immune system in patients with acute stroke in the brain multiple study parameters are assessed (we will integrate results from brain histopathology, flow cytometric characterization of T cell subsets, CITE-seq, and spatial single-cell RNA sequencing (spatial scRNA-seq) analyses).

Study description

Background summary

Despite novel acute therapies the global burden of stroke remains high worldwide. Targeting the immune response after stroke has the potential to improve recovery in all stroke patients. Experimental studies suggest important roles for T-lymphocytes, especially anti-inflammatory regulatory T cells, in the evolution of stroke and neurological deficit.

Study objective

1. To either confirm or refute the hypothesis that a subset of brain regulatory T cells exists in humans and expands after stroke.
2. To identify immunological biomarkers that can be used in stroke clinical trials targeting the adaptive immune system.

Study design

case control study.

Study burden and risks

In 60 patients blood will be sampled at 9 time points. In addition, neurologic examination at 5 time points, 1 MRI scan and 1 telephone interview will be performed. In 10 patients who undergo carotid endarterectomy, a lymph node will be extracted and blood will be drawn during this surgery. The study is carried out in both capacitated and incapacitated persons because exclusion of non-communicative stroke patients would lead to a selective patient sample.

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

In order to be eligible to participate in part 1 of this study (serial bloodsampling and cervical lymph node sampling), a subject must meet all of the following criteria:
- age 18 years or older,
- clinical symptoms of hemispheric ischemic stroke due to occlusion of a large vessel
- an onset of symptoms less than 48 h
- a score of 1 or more on the National Institutes of Health Stroke Scale (NIHSS)
- admission to hospital
- written informed consent obtained

For the control arm of the study:
- age 50 years or older,
- written informed consent obtained
- increased risk of cardiovascular disease (defined as a previous cardiovascular event other than stroke or one of the following risk factors: smoking, hypertension, hypercholesterolaemia, diabetes mellitus)

Exclusion criteria

- women of childbearing age
- patients with HIV, lymphoproliferative or immunological diseases
- infection at admission for which antibiotic therapy is initiated
- patients using immunosuppressive medication
- imminent death

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:	Completed
Start date (anticipated):	16-04-2021
Enrollment:	103
Type:	Actual

Ethics review

Approved WMO Date:	22-12-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-03-2021
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

No registrations found.

In other registers

Register	ID
CCMO	NL75373.018.20