Stroke-on-a-chip

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

Summary

ID

NL-OMON49951

Source
ToetsingOnline

Brief title
Stroke-on-a-chip

Condition

- Central nervous system vascular disorders

Synonym
cerebral infarction

Research involving
Human

Sponsors and support

Primary sponsor: Overige Ziekenhuizen
Source(s) of monetary or material Support: Dit pilotonderzoek wordt gefinancierd door onderzoeksgroep J. Hofmeijer te Rijnstate en UT

Intervention

Keyword: Cerebral ischemia, HiPSC, stem cells, Stroke

Outcome measures

Primary outcome

Primary outcome measure is network functionality, where a network is considered functional when a minimum of 1/3 of the electrodes shows activity, with a minimum of 6 spikes per minute per active electrode, and a minimum of one synchronous event per minute at eight weeks after plating.

Secondary outcome

- Electrophysiological responses to simulated *cerebral ischemia*

- Network and neuronal properties as studied by immunocytochemical analyses.

Study description

Background summary

To identify new, individualized, neuroprotective treatments for ischemic stroke, responses to ischemia of human neurons, including inter-individual variation, need clarification. By combining state of the art stem cell biology and organ-on-a-chip technology, we aim to derive neuronal networks of patients with brain infarcts and investigate the effects of simulated cerebral ischemia. Ultimately, we aim to identify new, individualized treatment targets.

Study objective

The primary objective is generation of functional neuronal networks from induced pluripotent stem cells (iPSCs) derived from patients with ischemic stroke. The secondary objectives are to measure neuronal network responses to simulated cerebral ischemia, estimate differences between patients and controls, and estimate variation amongst patients.

Study design

A prospective, experimental, case-control study in human blood.

Collection of heparin diluted blood samples (30cc per subject). Blood samples will be used for derivation of neuronal networks in the laboratory. All

subsequent experiments are with these neuronal networks in the lab. Patients will be treated according to local and national guideline for ischemic stroke. There will be no experimental / additional treatment for patients. Standard treatment or care will not be withheld.

Study burden and risks

Risks of blood sampling are considered negligible.

Contacts

Public
Selecteer

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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Age * 18y

* Clinical and radiological diagnosis of acute ischemic stroke
* Admission to stroke unit
* Capability to provide written informed consent

Exclusion criteria

* Any relevant systemic disease that is expected to interfere with a patient outcome within six months, such as malignancy
* Any progressive neurodegenerative disease
* Severe aphasia (informed consent not possible)

Study design

Design

Study type:	Observational non 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):	07-10-2020
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	12-03-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO Date:	04-01-2021
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	NL72176.091.19