A Functional Architecture of the Brain for Vision

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

Summary

ID

NL-OMON47844

Source
ToetsingOnline

Brief title
FAB4V

Condition

- Central nervous system vascular disorders

Synonym
stroke cva

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam
Source(s) of monetary or material Support: European Research Council

Intervention

Keyword: Brain, Neuropsychology, Stroke, Vision

Outcome measures

Primary outcome

Performance on experimental computerised tests of specific visual abilities and associated lesion characteristics.

Secondary outcome

- Performance on post-hoc tests of individual patients who show selective visual impairments to address hypotheses derived from the Goodale & Milner model and contrast them with predictions based on the patchwork model.

- Performance on neuropsychological tests that tap into different cognitive abilities such as memory or attention.

Study description

Background summary

The primary objective of this research programme is to develop a new functional architecture of the visual brain, based on two concepts: necessity and the theoretical framework of cortical networks.

In the last decades, electrophysiological and neuroimaging studies have identified more than 40 separate maps in the brain that are selectively tuned to specific visual features, such colour or motion. Brain-behaviour relationships based electrophysiology and functional neuroimaging are per definition correlational. We need neuropsychological research with patients who suffered focal brain damage to show us which brain structures are necessary (e.g. Catani & Stuss, 2012). A structure is deemed necessary when a lesion in that structure has a selective detrimental effect on the execution of that function.

Next, the proposed research programme will investigate how these necessary maps are linked together. As a theoretical perspective, this programme adopts a critical position towards the *what and where pathways* model developed by Goodale & Milner (1992), the current gold standard. Goodale & Milner postulated two major pathways; one for processing visuospatial information for motor programming, and one for visual recognition and memory. Recently, De Haan and Cowey (2011) suggested an alternative model in which the maps are thought to be organised in multiple overlapping networks.

This research programme represents one of the most comprehensive neuropsychological programmes ever proposed for the investigation of the visual domain. The lesion study entails a large-scale, cohort-study involving four academic medical centres in the Netherlands. The Netherlands is uniquely placed for such a programme with four excellent teaching hospitals in close vicinity and a high density of high-field neuroimaging facilities. The ERC grant will furnish the resources to carry out the proposed studies and to set up a collaborative network that will remain an asset for future large-scale neuropsychological investigations.

Catani, M. & Stuss, D.T. (2012) Cortex, 48, 1-6.
De Haan, E.H.F. and Cowey, A. (2011) Trends in Cognitive Sciences, 15, 460-466.
Goodale, M.A. & Milner, A.D. (1992) Trends in Neuroscience, 15, 20-25.

Study objective

The primary objective of this research programme is to develop a new functional architecture of the visual brain based on two concepts: the methodology to establish necessity and the theoretical framework of cortical networks. In addition, this project will investigate the frequency and severity of (visual) cognitive impairments following ischemic stroke and their effect on long-term outcome.

Study design

We propose a large-scale cohort study in a series of consecutive patients who suffered from ischemic stroke. This study will be implemented in four academic medical centres in the Netherlands.
Participation involves 1) an intake including a neuropsychological screening (1 - max. 1.5 hours), b) MRI scan (45 minutes + 15 minutes preparation), and c) computerised tests of specific visual abilities (visual test battery; 1.5 hours). Testing can take place from the sub-acute phase until several months after stroke, as long as the behavioural testing and the neuroimaging coincide in time. Single cases with selective deficits will be studied in depth using ad hoc developed testing procedures to explore the constellation of impaired and spared abilities.
A control group of 200 participants will be collected as a reference sample for

the experimental tests and for a subgroup also MRI.

Study burden and risks

The proposed project is an observational study with no known health risks. The participant may experience discomfort during the MRI session, or during the neuropsychological examination as this might be tiring. To minimize these discomforts a) we will provide extensive information on MRI scanning; b) the participant will have the possibility to pause the neuropsychological assessment at any time or complete it on another day if necessary.

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

All participants must meet the following criteria in order to be eligible to participate in this study:
- Age between 18 and 90 years;
- Dutch speaking., Additional inclusion criteria patient population:
- Stroke patients are eligible if they had ischemic stroke. The diagnosis of stroke will be made by an experienced neurologist based on the presence of an acute focal deficit and/or an associated lesion on computed tomography (CT) or magnetic resonance imaging (MRI);
- Patients with demonstrable or subjective visual impairments due to suspected brain damage (e.g. tumours, head injury) are also eligible.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- History of alcohol or drug abuse;
- Psychiatric disorders which could affect / have affected cognitive function;
- Neurological history (exception: for the patient population a history of previous stroke is not an exclusion criterion);
- Any other non-neurological disorder influencing cognitive functioning;
- Pre-existent cognitive decline as defined by a score of 3.6 or higher on the short Informant Questionnaire on Cognitive Decline in the Elderly-IQCODE Dutch version);
- Pre-existent dependency in activities of daily living., Additional exclusion criteria patient population:
- Inability to be examined post-stroke due to severe disturbances in consciousness or inability to comprehend task instructions;
- Contra-indication for MRI scanning.

Study design

Design

Study type:	Observational 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):	03-11-2015
Enrollment:	1400
Type:	Actual

Ethics review

Approved WMO Date:	30-06-2015
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	21-09-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-07-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-02-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-04-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-11-2019
Application type:	Amendment
Review commission:	METC NedMec

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	NL46715.041.14