Organization of the visual and auditory systems in hemispherectomized patients

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON42084

Source
ToetsingOnline

Brief title
Sensory organization after brain surgery

Condition

- Neurological disorders congenital
- Structural brain disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
"removing or disconnecting one half of the brain", hemispherectomy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Auditory system, Hemispherectomy, Neuroimaging, Visual system

Outcome measures

Primary outcome

The main study parameters are the performance on visual and auditory functions, the cortical activation during visual and auditory processing, and the course of the white matter tracks in the individual patients.

Secondary outcome

Secondary outcome parameters are the group-averaged measures of the above described primary outcome parameters and the comparison to the healthy controls.

Study description

Background summary

There remain important limitations to our knowledge of how the human brain endows us with perception and how this ability develops and changes with age. In particular, we have a very limited understanding of the role and cause of anatomical and functional hemispheric asymmetries (i.e. lateralization) in the visual and auditory systems. Therefore, we aim to study a unique group of patients in which one hemisphere is removed or disconnected (hemispherectomized patients) to gain more insight into the lateralization of the visual and auditory systems, and the adaptations of these systems after brain damage and brain surgery. We hypothesize that a) depending on the age of brain damage onset and on which hemisphere is removed, functions are found in the remaining hemisphere that are normally expected to be located in the removed hemisphere, b), the remaining hemisphere has abnormal retinotopic maps and c) functions that normally require two hemispheres can - to a certain extent - still be performed following a hemispherectomy.

Study objective

Our objective is to obtain insight into whether and how the visual and auditory

systems of hemispherectomized patients have adapted after brain damage and brain surgery in early life. For this purpose we will perform psychophysical tests and (functional) Magnetic Resonance Imaging ((f)MRI) directed at visual and auditory functioning. We will relate our findings to the etiology, to the age at which the brain damage occurred, to the age at which the hemispherectomy was performed, to the epilepsy duration, and to which hemisphere is removed or disconnected.

Study design

The study will be an observational study; a cross-sectional case-control design with cases and controls matched for age and gender. The study will contain four parts: 1) a functional questionnaire, 2) psychophysical measurements, 3) an (f)MRI experiment, including Diffusion Tensor Imaging, and 4) additional tests.

Study burden and risks

There are no risks associated with this study. Participants will be exposed to standard clinical test and an (f)MRI experiment with a magnetic field of 3 Tesla and fast fluctuating magnetic gradients and radiofrequency fields. These field strengths are common in fMRI and MRI research. Up till now no side effects have been reported and hemispherectomy patients have been studied with fMRI before, also without side effects. In rare cases an abdominal peripheral nerve will be stimulated because of the fluctuating magnetic fields. This results in a tickling, but harmless, feeling.

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

Patients:
- age 18 or older
- underwent hemispherectomy
Controls:
- age 18 or older
- subjectively healthy

Exclusion criteria

Patiënten:
- seizures
Controls:
- visual impairment
- hearing impairment

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:	Recruitment stopped
Start date (anticipated):	21-12-2015
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	31-12-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-08-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL49998.042.14