Localizing the eloquent cortex in children with epilepsy: Development and validation of a child-friendly fMRI protocol

Published: 20-07-2016
Last updated: 31-12-2024

Develop and implement a new functional MRI protocol for function mapping in young children.

Ethical review	Approved WMO
Status	Completed
Health condition type	Seizures (incl subtypes)
Study type	Observational invasive

Summary

ID

NL-OMON46983

Source
ToetsingOnline

Brief title
Localizing the eloquent cortex in children with epilepsy

Condition

- Seizures (incl subtypes)

Synonym
epilepsy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Janivo Stichting (via Stichting Vrienden

WKZ)

Intervention

Keyword: epilepsy, fmri, function-mapping, surgery

Outcome measures

Primary outcome

- Similarity amongst fMRI activation patterns of healthy controls

- Match between fMRI activation pattern and standard diagnostic results in

epilepsy patients

Secondary outcome

NVT

Study description

Background summary

For children with epilepsy, epilepsy surgery (i.e. surgical removal of the source of the seizures) can be a highly effective treatment. Before surgery is performed, it is crucial to know the lateralization and localisation (together *mapping*) of essential brain areas, for example for movement or language, in order to prevent damage due to surgery. Functional MRI is one of the most precise non-invasive tools that can be used for localising brain areas, and is increasingly applied in the presurgical work-up of adult epilepsy patients. For children, however, it is not always possible to obtain reliable fMRI results, because current fMRI protocols are developed for adults and do not match the interests, level of functioning and the experience of (young) children. In the current project, we aim to make high quality functional mapping available for young pediatric epilepsy patients. Having a reliable tool for function mapping in this group will reduce the need for more invasive function localization procedures, increase the number of children eligible for surgery, and optimize surgical decision making and the outcome of the eventual epilepsy surgery.

Study objective

Develop and implement a new functional MRI protocol for function mapping in

young children.

Study design

Observational study.

Study burden and risks

No direct benefits are expected for the subjects of the current study, but the study is expected to contribute to the availability of high-quality functional mapping for future pediatric epilepsy patients. After informed consent, subjects will fill out two questionnaires (Edinburgh Handedness Inventory to determine left-right handedness, and fMRI safety screening form). All children will perform a practice scanning session in a *mock-scanner* (no field) before the actual scan, in order to familiarize them with the MRI setting and practice the tasks. Subsequently, subjects will perform an fMRI session (3Tesla). There are no known risks associated with fMRI acquisition and the risk and burden of participating in the study are considered negligible.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Pilot phase and phase 2:
- Healthy subjects (m/f)
- Age 6-10;Phase 3:
- Epilepsy patients (m/f) scheduled for epilepsy surgery
- Age 6-10 or older with a mental age equivalent to this age range. The patients neurologist/neuropsychologist will decide whether older patients meet this criteria by evaluating the results of the patients neuropsychological assessment which includes IQ testing with for example the WPPSI-III-NL or WISC-III-NL. These tests are part of the clinical examination procedures and are performed by all epileptic patients who might require surgery

Exclusion criteria

- Metal objects in the body that are not MRI compatible
- Anxiety in the scanner (evaluated by parent/caretaker, or after practice in mock scanner)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL
Recruitment status: Completed

Start date (anticipated):	27-12-2016
Enrollment:	78
Type:	Actual

Ethics review

Approved WMO Date:	20-07-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-09-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-10-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	07-01-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL57524.041.16

Study results

Date completed: 17-07-2018

Results posted: 19-08-2021

First publication
01-01-1900