Clinical implementation of advanced MRI techniques for localization and monitoring of sensorimotor and cognitive functions in patients with brain tumors

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This study is aimed at two objectives: Objective 1: Development of new clinical fMRI protocols, based on existing cognitive tasks, that provide robust and reliable activation patterns, as well as performance measures that correlate woth…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON44896

Source
ToetsingOnline

Brief title
Clinical implementation of advanced MRI techniques

Condition

- Other condition

Synonym
brain tumor, glioma

Health condition

hersentumoren (meningioom en laaggradige gliomen)

Research involving

Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: braintumor, cognition, fMRI

Outcome measures

Primary outcome

study 1.1: development of cognitive test paradigms suitable for fMRI, that provide behavioral measurements that correlate with neuropsychological performance

study 1.2: application in healthy controls of cognitive fMRI protocols based on the best performing test paradigms from study 1.1 in order to test for robustness and reliability

study 2.1: application in patient cohorts of cognitive best performing fMRI protocols developed in study 2.1 to test for correlation of brain activity measures that correlate significantly with neuropsychological performance.

Secondary outcome

NA

Study description

Background summary

Patients with brain tumors frequently suffer from cognitive impairments that have a negative influence on their daily functioning and quality of life. These cognitive impairments can be a direct consequence of the tumor, but they can also be a temporary or sometimes even long-term side-effect of the surgical treatment. To date, unfortunately, we know very little about the causes of these impairments or the influence of treatment. There is a clear clinical need to acquire this knowledge to improve patient counselling and optimize surgical treatment. Currently available clinical tools for this purpose are not sufficient.
Promising new techniques that are available to increase our knowledge are non-invasive functional neuroimaging techniques such as fMRI. fMRI can provide detailed information that can be used to monitor changes over time in brain activity in brain tumor patients. In this research we aim first to develop clinical fMRI protocols for brain tumor patients that can test cognitive functioning, and ultimately provide information about expected cognitive functioning after surgery.

Study objective

This study is aimed at two objectives:
Objective 1: Development of new clinical fMRI protocols, based on existing cognitive tasks, that provide robust and reliable activation patterns, as well as performance measures that correlate woth neuropsychological functioning.

Objective 2: Development of new clinical fMRI protocols that provide brain activation measures that correlate with neuropsychological performance in patients over time.

Study design

Stage 1
study 1.1
cognitive tasks performed on PC by patients

study 1.2
fMRI in healthy controls using newly developed clinical fMRI protocols based on best performing cognitive tasks from study 1.1

Stage 2
study 2.1
fMRI in patients on best performing clinical fMRI protocols from study 1.2

Study burden and risks

The main measurement technique used in this study will is MRI. The Sint Elisabeth Hospital has ample experience with MRI scanning and the MRI-scanner

is handled by trained personnel. There are no known risks associated with MRI acquisition and the procedure is painless. The technique does not require administration of any contrast agent or ionizing radiation. Slight discomfort may occur due to noise generated by the scanner, or by lying still with the head and part of the body confined in a tunnel-like device. The subject will be provided with earplugs for protection from noise generated by the MRI scanner. An intercom is available in the scanner so the subject can remain in contact with personnel during the entire scan session. In addition, an emergency button is placed within reach of the subject during the scan session. If a subject is uncomfortable with any aspect of the procedure and wants to stop, the session will be terminated immediately.

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: Adult patients diagnosed with a glioma or meningioma, age 18 - 75
Healthy subjects: age 18 - 75

Exclusion criteria

Patients: metal objects in or around the body (braces, pacemaker, metal fragments) that are incompatible with MRI scan procedure
Healthy subjects: metal objects in or around the body (braces, pacemaker, metal fragments) that are incompatible with MRI scan procedure

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-07-2015
Enrollment:	330
Type:	Actual

Ethics review

Approved WMO

Date:	16-01-2015
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO

Date:	29-05-2017
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	09-05-2018
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL51147.028.14