Perioperative techniques for low grade glioma patients: validation of Diffusion Tensor Imaging tractography with subcortical stimulation and prediction of postoperative functional outcome with Resting State Functional Connectivity

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Observational invasive

Summary

ID

NL-OMON33478

Source
ToetsingOnline

Brief title
fMRI and DTI for low grade glioma surgery

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
low grade gliomas

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Diffusion Tensor Imaging, Electrical Stimulation Mapping, fmri, low grade glioma

Outcome measures

Primary outcome

The study aims at detection of critical brain areas for hand motor and language functions, that are normally located on the primary sensorimotor cortex (PSMC), supplementary motor cortex (SMC), Broca and Wernicke`s areas. Damage to either the PSMC, SMC, Broca and Wernicke*s areas can lead to (temporary) loss of motor and language functions, so all areas need to be identified by means of fMRI for optimal surgical planning. Subsequently, FT will be performed based on the DTI scan, and the corticospinal tract (CST, serving motor function), and the superior longitudinal fasciculus tract (SLF, serving language function) will be reconstructed. Then DTI-FT will be correlated with ioESM. RSFC analysis will be performed pre- and postoperatively to study the correlation between RSFC analysis, resected brain area and the functional outcome status of patients, as measured by neuropsychological, psychomotor and language tests.

Secondary outcome

Nvt

Study description

Background summary

Surgical resection of low grade gliomas prolongs survival and relieves symptoms. However, because resection may also affect eloquent brain areas, surgery comes with the risk of causing new neurological deficits. The gold standard for determining the location of eloquent areas of the cerebrum is intraoperative electrical stimulation mapping (ioESM), which does not yield preoperative information, and significantly lengthens the surgical procedure. Recently, functional Magnetic Resonance Imaging (fMRI) has been shown to be reliable in locating eloquent regions of the cortex, while Diffusion Tensor Imaging and Fiber Tractography (DTI-FT) can visualize the direction of fiber tracts in the subcortical white matter. By having both fMRI and DTI-FT information available in the operation room it becomes possible to map eloquent regions of the cortex and subcortex. However, DTI-FT has not been adequately validated.
If resection does affect eloquent areas, (worsening of) neurological deficits can occur. In a significant percentage of patients this neurological worsening turns out to be transient. A very probable explanation for the disappearance of symptoms over time is postlesional functional reorganization of the brain, a process that may be visualized using *resting state* fMRI. This technique can visualize patterns of functional connectivity (resting state functional connectivity: RSFC), which are shown to be different in healthy controls and patient populations in which neurological functioning is disrupted. However, whether these results can be conclusively correlated to the severity of postoperative neurological deficit and eventual recovery in low grade glioma patients remains to be established.

Study objective

This study is designed (1) to validate white matter tracts derived from DTI-FT with the results of ioESM, and (2) to develop RSFC analysis in order to quantify changes in functional connectivity patterns in patients that recover from neurosurgery-induced, transient, motor and language disabilities.

Study design

Our patients are scanned prior to surgery, 1 to 2 weeks after surgery, and 3 months after surgery. In this way we are able to assess anatomical (DTI-FT) and functional (RSFC) brain connectivity changes due to tumour (prior to surgery), due to resection (1 to 2 weeks after surgery), and the final outcome (3 months after surgery). Testing of motor, language and cognition of patients takes also place in the UMC in Utrecht with the same timeline as the scanning sessions (prior to surgery, 1 to 2 weeks after surgery, and 3 months after surgery).

These test findings are correlated to DTI-FT and RSFC findings to investigate whether there is a relationship between resection of critical anatomical tracts and functional areas and postoperative loss of motor and language functions (functional outcome of the patients). A group of healthy volunteers will be included to assess the test-retest reliablility of DTI-FT and RSFC. Because the motor, language and cognition tests are standardized, healthy volunteers are only scanned following the same timeline as for the patients.

Study burden and risks

There are no known risks associated with MRI acquisition. MRI has been used as a diagnostic, clinical tool for over twenty years now. FMRI, DTI and RSFC involve the same technique as clinical MRI, and thus pose no known risks for subjects. Furthermore, there are no known risks associated with the digital monitoring of (sub) cortical stimulation during surgery. Patients will have to come three times at the UMC therefore travel costs are refunded. Healthy volunteers will receive a financial compensation for their participation. Overall, patients are not expected to immediately benefit from the DTI and RSFC analysis results. However, it is well possible that in the (near) future these non-invasive procedures will become, just as fMRI, a useful tool in presurgical planning and planning during operation.

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

A) Inclusion criteria Patients with LGG:;1. Candidate for surgical removal of the brain lesion
2. Brain tumour in/near motor or language cortex;B)Inclusion criteria for healthy volunteers:;1. 25-70 years
2. Ability to perform the fMRI tasks

Exclusion criteria

A) Exclusion criteria Patients with LGG:;1. MRI-incompatible metal objects in or around the body (braces, pacemaker, metal fragments, surgical clips)
2. Significant cognitive deficits; non ability to perform the fMRI tasks
3. History of neurological or psychiatric illness, not related to the brain lesion ;B) Exclusion criteria Healthy volunteers:;1. Metal objects in or around the body (braces, pacemaker, metal fragments, surgical clips)
2. History of neurological or psychiatric illness
3. Cerebral abnormalities on screening MRI
4. Pregnancy as determined with a urine pregnancy test before functional MRI scanning (standard procedure for healthy volunteers at the UMC Utrecht)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-10-2009
Enrollment:	77
Type:	Actual

Ethics review

Approved WMO

Date:	23-10-2009
Application type:	First submission
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	NL27453.041.09