Realtime language mapping during awake brain surgery

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The primary goal is to compare functional (language) areas in the brain found by preoperative fMRI, to those found during intraoperative ESM (electrical stimulation mapping) and fUS (functional ultrasound) during awake craniotomies, to see whether...

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

Summary

ID

NL-OMON50885

Source
ToetsingOnline

Brief title
RELAY-study

Condition

- Nervous system neoplasms malignant and unspecified NEC
- Nervous system, skull and spine therapeutic procedures

Synonym
brain tumor, glioma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: HSTM grant

Intervention

Keyword: Glioma, Language, Ultrasound

Outcome measures

Primary outcome

The main study parameter for fUS is the mean correlation value ('r'), also known as the Pearson Correlation Coefficient. For every administered task, the mean correlation between the task pattern and the Doppler signal is calculated along with the mean correlation calculated outside the functional area as a reference correlation value. The functional areas found by fUS, ESM, and (preoperative) fMRI will be compared. The percentage of similar brain areas found by two techniques is what we call an accuracy. We look at three accuracies (outcomes): the fUS-ESM accuracy, the fUS-fMRI accuracy and the fMRI-ESM accuracy.

Secondary outcome

The secundary outcome is the score on language tests. These scores will be compared to intraoperative mapping results (ESM and fUS) and fMRI results. Additionally, comparisons will be made between preoperative (preoperative language tests-preoperative fMRI) and postoperative (postoperative language tests-postoperative fMRI).

Study description

Background summary

De standard treatment of patients with gliomas in functional brain areas is awake brain surgery with ESM (electrical stimulation mapping). The goal is to

resect as much tumor tissue as possible, while preserving as much function as possible. Even though language is monitored during these surgeries, more than 50% of the patients have postoperative language deficits (aphasia). These deficits result in a lower quality of life.

We would like to investigate if an extra intraoperative technique, functional ultrasound (fUS), can be used as an addition to the existing intraoperative language monitoring technique. This technique is based on (regular) ultrasound, which is used regularly during awake surgeries. fUS offers images at thousands of frames per second. Because of the high temporal resolution, this technique is sensitive for very small Doppler shifts (also called µDoppler), such as those caused by the moving blood inside brain vasculature. This technique can measure local increases of CBV (cerebral blood volume) as a result of neural activity. This is a continuation of a previous protocol in which the intraoperative application of fUS showed to be informative: fUS seems to be able to differentiate between functional and non-functional brain tissue. This is the application of the technique which we would like to investigate further, focussing on language specifically.

Study objective

The primary goal is to compare functional (language) areas in the brain found by preoperative fMRI, to those found during intraoperative ESM (electrical stimulation mapping) and fUS (functional ultrasound) during awake craniotomies, to see whether fUS can be used as an addition to the standard intraoperative language mapping with ESM.

Secondary Objectives:
- Identify different aspects of language functioning in the brain using fUS and a selection of language tasks.
- Relate intraoperative findings from language mapping to postoperative language outcome.
- Relate language outcome to pre and postoperative fMRI findings, and relate these timepoints to each other (preoperative language tests-preoperative fMRI vs. postoperative language tests-postoperative fMRI)

The main goal is to be able to perform an even more specific intraoperative language monitoring, in order to reduce postoperative language deficits and to improve the quality of life in this patient group in the future.

Study design

Preoperatively we will extend the standard fMRI with max. 30 min. During the fMRI specific language and motor tasks will be performed, which are similar to the intraoperative tasks.

Intraoperatively, we will identify and image functional and adjacent non-functional brain areas related to specific tasks using fUS, based on the functional map created by using intraoperative electrocortical stimulation mapping (ESM, the golden standard during routine awake craniotomy surgery). The tasks used will range from muscle movements to different language tasks. The imaging trial will last a total maximum of 20 min.

Postoperatively an extra fMRI scan will be planned (max 60 min) within 8 weeks, in which similar tasks will be performed as pre and intraoperatively. This scan will be combined with another appointment for which the patient has to visit the hospital, in order to avoid the need to visit the hospital only for the study.

Study burden and risks

Preoperativly: Considering that it is standard procedure to plan a preoperative fMRI, we don't expect that the extension of scan time will increase the burden for the patient considerably.

Intraoperatively: as functional mapping using ESM and Ultrasound is already an integral element of awake craniotomy surgery, the nature and extent of the burden for the patient remains very limited. The patient will have no burden of the imaging process using fUS and the specific tasks we will ask the patient to perform will be very similar to the tasks already performed during ESM. The tasks together will not take longer than 20 minutes, minimizing the extra time necessary for surgery. In addition, as fUS-imaging is very similar to any type of ultrasound imaging already used in a clinical setting and during awake craniotomy surgery, there will be limited additional risks associated with participation. Also, the exposure levels for the fUS imaging sequences (insonification with unfocussed beams) are well below FDA limits.

Postoperatively: The addition of an extra fMRI scan can increase the burden of the patient. However, since we will plan the scan on a day when the patient will already visit the hospital for a (standard) appointment, the patient does not need to visit the hospital specifically for the study. Because of this overlap, we think that the additional burden of an extra scan will be limited.

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

- Undergoing awake craniotomy for the indication of glioma removal with ESM (electrical stimulation mapping) already planned for the removal of the tumor
- Age >= 18 years
- Mentally competent
- Location of the tumor in or near a functional area (e.g. language, motor)
- Informed written consent

Exclusion criteria

- Depression or an anxiety disorder
- Inadequate level of Dutch
- History of a medical, neurological or psychiatric condition known to affect language or cognitive functioning
-(History of) substance abuse
-Use of medication known to influence language or cognitive functioning (other than anti-epileptic drugs)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2021
Enrollment:	45
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-05-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL77240.078.21