Functional Ultrasound (fUS)- and fMRI-imaging in Patients with a Skull Bone Defect (SBD)

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The main objective of this study is to further validate our fUS-technique by comparing and contrasting the spatial and temporal patterns of fUS-defined functional areas with results acquired using fMRI in the same human subject.

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

Summary

ID

NL-OMON51319

Source
ToetsingOnline

Brief title
fUS-fMRI SBD Study

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
brain tumor, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: NWO-Groot voor CUBE (Centre for Ultrasound Brain Imaging @ Erasmus MC)

Intervention

Keyword: fMRI, functional ultrasound, skull bone defect

Outcome measures

Primary outcome

As mentioned, the primary goal of this study is to compare and contrast the spatial and temporal patterns of fUS-defined functional areas with results acquired using fMRI.

We will do so using two primary study parameters:

1) Spatial comparison between fUS- and fMRI- functional maps, using:

a. the dice coefficient (DC): giving a value between [-1, 1], with -1 indicating *no agreement between the fUS- and fMRI-map* and 1 indicating *complete agreement between the fUS- and fMRI-map*

b. the spatial correlation (SC): giving a value between [-1, 1], with -1 indicating *no agreement between the fUS- and fMRI-map* and 1 indicating *complete agreement between the fUS- and fMRI-map*

c. the centre-of-mass error (CE): the outcome is a value in millimeters (mm) as a measure of discrepancy between the centre of mass of the fUS- vs. fMRI-defined functional maps.

2) Temporal comparison between fUS and fMRI, using:

a. the rise-time difference (ΔRT): the outcome is a value in seconds, indicating the difference in average rise time between the average fUS- and fMRI-based functional signal

b. the fall-time difference (ΔFT): the outcome is a value in seconds, indicating the difference in average fall time between the average fUS- and fMRI-based functional signal

c. the difference in average ON-time (ΔO): the outcome is a value in seconds, indicating the difference in average ON-time between the average fUS- and fMRI-based functional signal

d. the difference in average OFF-time (ΔO): the outcome is a value in seconds, indicating the difference in average OFF-time between the average fUS- and fMRI-based functional signal

Secondary outcome

The secondary study parameters involve:

1) the different imaging parameters that we wish to test in a systematic fashion to further optimize image quality and image acquisition for future studies. This endeavour is not statistical but will involve qualitative scoring of image quality and functional signal acquisition under different imaging parameters.

2) the extent of within-subject reproducibility of the image quality and functional signal in the same functional task and functional region. This is one of the main benefits of performing fUS in a SBD-setting as compared to the intra-operative setting, where time is very limited. We will compare image and signal quality in a qualitative manner across a maximum of 6 sessions, as a first-ever comparison of repeated in-human fUS-measurements.

Study description

Background summary

Functional Ultrasound (fUS)-imaging is a new imaging modality combining unique spatiotemporal resolution and penetrative depths with ease of use and intra-operative applicability. In a currently ongoing study in the OR-setting, we have applied functional Ultrasound (fUS)-imaging during neurosurgical procedures as a new means of imaging tumor and functional brain tissue. So far, fUS shows very promising functional and vascular results. However, for the technique to reach clinical maturity, further validation and understanding of especially the functional, hemodynamic signals is immensely valuable. The current clinical gold standard for haemodynamics-based functional imaging is functional Magnetic Resonance Imaging (fMRI). Being able to compare spatial and temporal characteristics of our fUS-signal to fMRI-signal would be very valuable cross-validation. However, the OR-setting very limiting in terms of time and logistics. In this study we propose combining fUS and fMRI measurements in an outpatient setting in subjects with a skull bone defect (SBD), either with or without a plastic (e.g. PEEK) skull implant. Measuring subjects with SBDs is particularly beneficial as 1) fUS, like all ultrasound techniques, does not work well through an intact skull, requiring access to the brain through a natural/surgical opening and 2) working with patients with an already existing SBD in an outpatient setting allows for the necessary time to optimize technical parameters during signal acquisition, and to repeat measurements multiple times to gather larger amounts of data for powerful analyses.

Study objective

The main objective of this study is to further validate our fUS-technique by comparing and contrasting the spatial and temporal patterns of fUS-defined functional areas with results acquired using fMRI in the same human subject.

Study design

Observational Study

Study burden and risks

The subject will have no significant burden of the imaging process using fUS, other than time investment. The majority of tasks we will ask the subject to perform will be very similar to tasks that are usually performed in for example the fMRI and form no burden. The tasks together will not take longer than 60 minutes for each imaging session, with a maximum of 6 sessions in total (depending on the quality of the data). Sessions will be planned according to

the volunteer*s schedule, as much as possible. Additionally, the exposure levels for the fUS imaging sequences (insonification with unfocussed beams) are well below FDA limits and what is used in clinical scanners using focussed transmissions.
Patients will also be asked to undergo one structural MRI session (optional) and one fMRI session. The MRI session will be a maximum of 30 min. to acquire recent, structural data on the patient*s face and head contour after PEEK. The patient will only be subjected to this session if there are no recent, post-PEEK MRIs available from the clinical setting. The fMRI session will be a maximum of 60 min. and will consist of simple, functional paradigms similar to those conventional in the clinical setting, such as small motor tasks (with or without concomitant EMG-measurements), visual tasks or language-related tasks. The fMRI session will be performed somewhere during the 6 fUS-sessions in accordance with the patient*s schedule. Because the total scanning time in the MRI-scanner will be contained to a maximum of 90 min., spread out over two sessions, we think this burden can be considered to be reasonable. Subject participation in the study will, however, lead to the benefit of further determining and increasing the potential use of fUS as a new and highly powerful imaging tool, which has the ability to present areas of functional tissue deep inside the brain.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Adult (> 18 years)
- Temporary or chronic bone defect in the skull (with a size of >50% of probe diameter), either with
or without a plastic skull implant
- Mentally competent to follow instructions during imaging

Exclusion criteria

- Active infection of surrounding bone/plastic implant/brain tissue
- Contra-indication to undergo fMRI-scan (due to e.g. an implant or claustrophobia)
- Mental incompetence

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2022
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Cube Clinic Mobile 1 (fUS-cart with Verasonics Vantage 256)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-05-2022
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	NL80307.078.22