FASTMRSI

Metabolic Characterization of Space Occupying Lesions of the Brain

NCT-Nummer:
NCT04233788

Studienbeginn:
Juni 2020

Letztes Update:
26.06.2020

Wirkstoff:
-

Indikation (Clinical Trials):
Brain Neoplasms

Geschlecht:
Alle

Altersgruppe:
Erwachsene (18+)

Phase:
-

Sponsor:
University Hospital Inselspital, Berne

Collaborator:
Swiss National Science Foundation

Studien-Informationen

Detailed Description:

Introduction - Recently the first commercially available 7T MR-scanner which is approved for clinical use came on to the market. The main motivation to go to higher field strengths is the fact that better SNR can be achieved in shorter acquisition time, or higher spatial resolution can be obtained in the same measurement time. High field MRI also has drawbacks, e.g. substantially higher specific absorption rate (SAR), higher susceptibility related image distortion problems, and longer longitudinal relaxation times. Nevertheless, moving to higher fields is especially beneficial for MR-spectroscopy. This is due to the fact that better signal to noise ration (SNR) is combined

with higher spectral resolution. The two most commonly used techniques for spectroscopic imaging (MRSI) are: (i.) relative slow 2D/3D techniques like PRESS and semiLASER based techniques, and (ii.) fast 3D echo planar based (EPI) techniques. Although echo planar spectroscopic imaging (EPSI) is a technique that has been introduced by Sir Peter Mansfield in the first half of 80es, the method is still continuously being improved, and recently very promising applications related to brain tumor diagnostics were published. To be mentioned in this context is the fact that the method can be combined with spectral editing for the detection of 2-hydroxy-glutarate (2HG) in glioma patients. 2HG is only present if the glioma that has mutations in the IDH-gene. It is shown that gliomas having the IDH-mutation have a much better overall survival prognosis. Apart from brain tumor typing, high resolution EPSI imaging also enables investigation the investigation of tumor infiltration using metabolic criteria. In surgery the patients' preoperative intake of the 5-aminolevulinic acid (5-ALA) before surgery selectively makes malignant glioma tissues fluorescent under blue light irradiation and tumor itself becomes clearly visible during the neurosurgical intervention. The fact that 5-ALA-guided completely-resected glioma patients have a significant longer survival time, underlines the necessity to know the exact tumor boundaries.

Aims - The major aims of the study proposed are manifold:

(i.) The development of a novel EPSI-pulse sequence utilizing 3D-radial k-space sampling schemes, that focuses on robustness w.r.t. patient motion, is robust with respect to chemical shift displacement artifacts, includes the possibility of 2HG-spectral editing, uses SAR-reduced radiofrequency (RF) pulses, and operate with total acquisition times that are acceptable for clinical routine use; (ii.) Comparison of the novel sequence with available conventional EPSI-techniques and semiLASER-based techniques for clinical routine use comparing its performance at 3T and 7T; (iii.) The development of a graphic processor unit (GPU) based fitting algorithm for quantification of 3D-radial EPSI-data based on the existing tdfdfit-algorithm; (iv.) Extension of a locally developed machine learning based automatic quality-filtering algorithm to be applied on the researchers' novel EPSI-data; (v.) Quantitative investigation on the effect spatial non-uniform transmit and receive properties for all relevant metabolites and spatial dependent signal amplitude correction schemes (extension of a locally developed method); (vi.) Investigation of the exact effects of selective excitation on J-coupled spin systems, and comparison of these effects between 3T and 7T; (vii.) Reproducibility study on 20 healthy volunteers measured twice with the same protocol (10 recorded twice at 7T and 10 recorded twice at 3T); (viii.) Pre-operative application of the best suited EPSI-pulse sequence in a total of 75 patients. All patients will be recorded at 3T as well as at 7T using the equivalent protocols; (ix.) Co-registration of pre-operative, spatially resolved 3D-EPSI-MRSI data with post-operative 3D-FLAIR and T1c-imaging in IDH-wildtype patients with had complete resection during 5-ALA guided neurosurgical interventions will provide information on whether MRSI-techniques are helpful to predict the tumor affected volume; (x.) Documentation of the location of a biopsy, histology to enable a better correlation between MR-spectroscopic patterns and histology.

(xi) Comparison of the performance of CEST versus the CMRR-semiLASER MRSI sequence w.r.t. to the prediction accuracy of the IDH-type of the glioma by the two technologies.

Methodology - The implementation of a robust EPSI sequence that uses 3D-radial k-space sampling schemes and reconstruction will be performed on Siemens IDEA developer platforms for VE- and XA-software versions. The sequence will be compared to the performance obtained with

another EPSI implementation, available via Siemens, as well as the CMRR-implementation of the MEGA (MEscher-GArwood) semi-LASER (Localization by Adiabatic SElective Refocusing) for 2HG-editing (CMRR Spectroscopy Package, 2012). The quantification of the EPSI-data of the reference sequence will be performed with the MIDAS package. The EPSI-data of the novel sequence as well as MEGA-semi-LASER sequence will be quantified using a parallelized GPU-re-implementation of the tdfdfit-algorithm made available as separate plugin within jMRUI-spectroscopy package (jMRUI: java magnetic resonance user interface). Co-registration of pre-surgery EPSI-data with post-operative structural MRI-data will be performed with the SPM (Statistical Parameter Mapping) program. Further statistical analysis and machine learning algorithms will be based on statistical programming language "R". The CEST pulse sequences will be obtained via Siemens-Healthineers.

Potential significance - (a.) Pre-surgical knowledge of the IDH-status will enable better individual neurosurgical treatment of the patient; (b.) Coregistration of metabolic EPSI-data, with post-operative structural MR-data will give information on the fundamental usefulness of MRSI-techniques to detect glioma infiltration zones; (c.) Improved follow-up of IDH-mutated glioma patients, who typically have a long period of minimal progression, followed rapidly by aggressive growth and transformation to higher grade; (d.) The availability of an imaging biomarker to monitor tumor recurrence would be a major advance for all glioma patients.

Ein-/Ausschlusskriterien

Inclusion Criteria:

- Healthy people who are able to lie in the MR scanner for one hour;

- Patients with suspected mass in the brain

- Written informed consent

Exclusion Criteria:

- Persons under the age of 18

- Persons who are mentally unable to choose to participate

- Pregnant women

- Patients with oncological findings or neurodegenerative findings in the past

- Wearing active implants (e.g. pacemakers and neurostimulators)

- Emergency patients

- Persons with tattoos on the head or neck area

Studien-Rationale

Primary outcome:

1. Optimal MR-sequence for IDH-typing (Time Frame - 48 months):
Finding the most optimal (2HG-edited, radial kspace-sampled) EPSI MRSI/CEST technique for the initial diagnosis of gliomas with respect to IDH-typing. Pre-operative knowledge of the IDH-type is important information for further neurosurgical treatment.

Secondary outcome:

1. Spectral/CEST pattern (Time Frame - 48 months):
The retrospective analysis of tumor affected tissue volumes identified by 3D-MRSI/CEST image data with the factual resected volumes during 5-ALA guided complete tumor resection interventions enable to find the relationship between the spectral or CEST pattern and the location of the glioma.

Studien-Arme

- Patient Group 1 (15 Patients)
  First two pulse sequence will be applied to this group at a 3T Prisma and a 7T Terra scanner. Best sequence propagates to Patient Group 2.
- Patient Group 2 (15 Patients)
  Two pulse sequence (one will be the best performing pulse sequence of Patient Group 1) will be applied to this group using a 3T Prisma and a 7T Terra scanner. Best sequence propagates to Patient Group 3.
- Patient Group 3 (15 Patients)
  Two pulse sequence (one will be the best performing pulse sequence of Patient Group 2) will be applied to this group using a 3T Prisma and a 7T Terra scanner. Best sequence propagates to Patient Group 4.
- Patient Group 4 (15 Patients)
  Two pulse sequence (one will be the best performing pulse sequence of Patient Group 3) will be applied to this group using a 3T Prisma and a 7T Terra scanner. Best sequence propagates to Patient Group 5.
- Patient Group 5 (15 Patients)
  Two pulse sequence (one will be the best performing pulse sequence of Patient Group 4) will be applied to this group using a 3T Prisma and a 7T Terra scanner. At the end the best performing sequence will result.
- Healthy Control Group 1 (10 Persons)
  First two pulse sequences will be applied to this group using a 3T Prisma and a 7T Terra scanner. Data will be used as normative data.

- Healthy Control Group 2 (10 Persons)
  First two pulse sequences (one will be the best performing pulse sequence of Healthy Control Group 1) will be applied to this group using a 3T Prisma and a 7T Terra scanner. Data will be used normative data.
- Healthy Control Group 3 (10 Persons)
  First two pulse sequences (one will be the best performing pulse sequence of Healthy Control Group 2) will be applied to this group using a 3T Prisma and a 7T Terra scanner. Data will be used as normative data.
- Healthy Control Group 4 (10 Persons)
  First two pulse sequences (one will be the best performing pulse sequence of Healthy Control Group 3) will be applied to this group using a 3T Prisma and a 7T Terra scanner. Data will be used normative data.
- Healthy Control Group 5 (10 Persons)
  First two pulse sequences (one will be the best performing pulse sequence of Healthy Control Group 4) will be applied to this group using a 3T Prisma and a 7T Terra scanner. Data will be used normative data.

Geprüfte Regime

- MR-scans using a 3T Prisma and a 7T Terra scanner (Siemens, Erlangen Germany) (Examined are fast MRSI sequences and CEST sequences.):
  The MR-scans performed at 3T and 7T are performed to evaluate whether high field MR-examinations bring an advantage to the patient in determining the IDH-status of the glioma. Two MRSI/CEST sequences will be tested against each other.

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Studienlocations (1 von 1)

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Status: Rekrutierend

Quelle: ClinicalTrials.gov