Trial Description

Title

Test-retest reliability of quantitative MRI parameters in a prospective single-center neurooncological imaging study

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

[---]*

Brief Summary in Scientific Language

Radiomics, a recent field of research in medical imaging, investigates the potential value of quantitative imaging parameters in medical decision making. Radiomics in the context of neurooncological imaging focusses on the automated extraction and analysis of a multitude, usually thousands of quantitative imaging parameters in order to gain additional insight into tumor biology. The ultimate goal of radiomics is the development of novel prognostic models in neurooncology by adding quantitative data and machine-learning approaches to conventional qualitative image analysis. Therefore, we aim to investigate the test-retest reliability of quantitative MRI parameters in a prospective single-center group (n=52) of patients with neurooncological diagnosis and routine follow-up head MRI imaging including several anatomical imaging volumes (contrast-enhanced T1, FLAIR, T2-TSE) that will be acquired twice. As a result, we aim to identify quantitative MRI parameters that can be reliably measured in brain neoplasms.

Organizational Data

- **DRKS-ID:** DRKS00011651
- **Date of Registration in DRKS:** 2017/01/27
- **Date of Registration in Partner Registry or other Primary Registry:** [---]*
- **Investigator Sponsored/Initiated Trial (IST/IIT):** yes
- **Ethics Approval/Approval of the Ethics Committee:** Approved
- **(leading) Ethics Committee Nr.:** S-632/2016 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg
Secondary IDs

Health condition or Problem studied

- Free text: *Intra-session test-retest reliability of quantitative MRI parameters in neurooncological MRI imaging of the brain*
- ICD10: C71 - Malignant neoplasm of brain

Interventions/Observational Groups

- Arm 1: *We aim to investigate the test-retest reliability of quantitative MRI parameters in a prospective single-center group of patients with neurooncological diagnosis and routine follow-up head MRI imaging including several anatomical imaging volumes (contrast-enhanced T1, FLAIR, T2-TSE) that will be acquired twice. As a result, we aim to identify quantitative MRI parameters that can be reliably measured in brain neoplasms.*

Characteristics

- Study Type: Interventional
- Study Type Non-Interventional: [---]*
- Allocation: Single arm study
- Blinding: [---]*
- Who is blinded: [---]*
- Control: Uncontrolled/Single arm
- Purpose: Diagnostic
- Assignment: Single (group)
- Phase: N/A
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): N/A

Primary Outcome

intraclass correlation coefficient of quantitative MRI parameters

Secondary Outcome

none
Countries of recruitment

- DE Germany

Locations of Recruitment

- University Medical Center Neuroradiologie, Heidelberg

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/01/16**
- Target Sample Size: **52**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- age > 18
- capacity to consent to treatment as defined under German law
- supratentorial intraaxial or mainly supratentorial intraaxial tumor that has been histologically proven
- supratentorial contrast enhancement ≥ 3 x 3 x 3 mm
- appointment for routine follow-up MRI of the brain
- isovolumetric contrast-enhanced and isovolumetric T1w volume in routine follow-up MRI imaging

Exclusion criteria

- pregnancy
- inflammatory CNS disease
- pronounced motion artefacts
- adipositas per magna

Addresses
Primary Sponsor

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Sources of Monetary or Material Support

- Institutional budget, no external funding (budget of sponsor/PI)

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Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2017/03/31

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) Ethikvotum
- trial protocol (mandatory for transfer to Studybox) Protokoll zum Ethikantrag
- Background literature Kickingeder, P., et al., Radiomic Profiling of Glioblastoma: Identifying an Imaging Predictor of Patient Survival with Improved Performance

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.