Trial Description

Title
Pre-operative advanced MR imaging in children

Trial Acronym
paMRic-study

URL of the trial
[---]*

Brief Summary in Lay Language

Brain tumors are the most common solid tumors in children, and the initial operative therapy determines not only long-term outcome, but also the rate and extent of neurological deficits. This is also true for patients with structural epilepsy. Optimal planning of this operation therefore is crucial; to this effect, advanced imaging methods are most important. Using modern approaches such as functional and diffusion magnetic resonance imaging (fMRI, dMRI), it is possible to identify brain regions involved in certain brain functions. This again allows for a more individual planning of an ensuing operation. These approaches are already in routine use for special indications in adults. However, this is not the case for children in whom these approaches are, for a number of reasons, more difficult to apply. This study is aimed at assessing the routine feasibility of such investigations in children.

Brief Summary in Scientific Language

Brain tumors are the most common solid tumors in children, and the initial operative therapy determines not only long-term outcome, but also the rate and extent of neurological deficits. This is also true for patients with structural epilepsy, as induced by e.g. malformations of cortical development. Optimal planning of this operation therefore is crucial; to this effect, advanced imaging methods are most important. Using modern approaches such as functional and diffusion magnetic resonance imaging (fMRI, dMRI), it is possible to identify brain regions involved in certain brain functions. This again allows for a more individual planning of an ensuing operation. These approaches are already in routine use for special indications in adults. However, applying these methods in children requires substantial expertise with regard to planning, execution, and interpretation. This combined interdisciplinary expertise is only available in select centers. This study is therefore aimed at assessing the routine feasibility of such investigations in children at a tertiary referral center.

Organizational Data

- DRKS-ID: DRKS00006738
- Date of Registration in DRKS: 2014/09/26
Secondary IDs

Health condition or Problem studied

- Free text: brain tumors (benign, malignant, or unclear)
- Free text: structural epilepsy
- ICD10: G40 - Epilepsy
- ICD10: D33 - Benign neoplasm of brain and other parts of central nervous system
- ICD10: C71 - Malignant neoplasm of brain
- ICD10: D43 - Neoplasm of uncertain or unknown behaviour of brain and central nervous system

Interventions/Observational Groups

- Arm 1: individually-tailored, pre-operative examination using advanced MR methods
  - additionally, depending on endangered system, pre- and postoperative language testing, structured clinical exam or opthalmological examination will be performed

Characteristics

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

Primary Outcome
Feasibility of preoperatively examining the language domain using advanced MRI methods (in particular, functional MRI) in children with brain tumors or structural epilepsy. Feasibility is defined as the ratio of successfully performed, interpretable exams.

Secondary Outcome
Feasibility of preoperatively examining the sensorimotor and the visual system using advanced MRI methods (in particular, diffusions MR tractography) in children with brain tumors or structural epilepsy. Feasibility is defined as the ratio of successfully performed, interpretable exams.

Countries of recruitment
■ DE Germany

Locations of Recruitment
■ University Medical Center Kinderklinik, Abteilung Neuropädiatrie, Tübingen

Recruitment
■ Planned/Actual: Planned
■ (Anticipated or Actual) Date of First Enrollment: 2014/09/30
■ Target Sample Size: 80
■ Monocenter/Multicenter trial: Monocenter trial
Planned/Actual: **Planned**  
(Anticipated or Actual) Date of First Enrollment: **2014/09/30**

Target Sample Size: **80**

Monocenter/Multicenter trial: **Monocenter trial**

| National/International: **National** |

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### Inclusion Criteria

- **Gender:** Both, male and female
- **Minimum Age:** 6 Years
- **Maximum Age:** 18 Years

### Additional Inclusion Criteria

- Epileptogenic or tumorous lesion in the central region OR in cortical language regions OR near the optic radiation with given or possible indication for neurosurgery

### Exclusion criteria

- metal implants (vascular clips or coils, orthopedic screws, cardiac pacemakers, shunts) unless explicitly and in writing certified to be MRI compatible
- orthodontic brackets (removal may be required for clinically-indicated MRI exams, but will not be performed solely for study-related MRI exams)
- history of injuries possibly introducing metal into the body (high-speed trauma, shrapnel, metal workers etc.)
- pregnancy (a pregnancy test will be required for all girls > 12 years in case of anamnestic doubts)

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### Addresses

<table>
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Sources of Monetary or Material Support

- Private sponsorship (foundations, study societies, etc.)

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Status

- Recruitment Status: Recruiting ongoing
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

* 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.