Trial Description

Title

Design and implementation of a national multicenter registry for pediatric patients with CNS lesions treated with robotic radiosurgery

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The CyberKnife registry for pediatric patients with CNS lesions is designed as an interdisciplinary multicenter observational study intending to include patients on both, a retrospective and prospective basis. Epidemiologic, treatment, clinical and imaging data will be collected in each participating center. The main interest of the registry is to deliver informations about outcome, side effects and long-term effects of this rare treatment form in children. Furthermore the registry aims to serve a s a basis for establishing entity-related treatment protocols and intermethodic comparisons. It will sustain quality and optimization of these radiosurgical treatment proceedures.

Brief Summary in Scientific Language

Pediatric CyberKnife registry for treatment of CNS lesions. The registry allows precise observation of treatment results, side effects and long-term effects of this specific type of radiosurgery. The treatment scope are distinct cns lesions of tumoral or vascular origin within the CNS, inclusing metastases.

Organizational Data

- DRKS-ID: **DRKS00016973**
- Date of Registration in DRKS: **2019/03/18**
- 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.: **EA2/232/17 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- Free text: **brain tumors**
- ICD10: **Q28.2 - Arteriovenous malformation of cerebral vessels**
- ICD10: **D33 - Benign neoplasm of brain and other parts of central nervous system**
- ICD10: **C71 - Malignant neoplasm of brain**
- ICD10: **C72 - Malignant neoplasm of spinal cord, cranial nerves and other parts of central nervous system**
- ICD10: **D33.4 - Benign neoplasm: Spinal cord**

Interventions/Observational Groups

- Arm 1: **The CyberKnife Registry is an observational study, intending to register all pediatric patients who have been treated with Cyberknife radiosurgery for lesions in the central nervous system. Precise documentation of clinical, therapeutic and outcome data allows a acientific evaluation of this method, specifically in children. The registry records side effects and long-term effects. It allows quality control of treatment procedures and derivation of new therapy protocols.**

Characteristics

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

Primary Outcome

Primary endpoints are complete remission and recidive at 1 and 2 years of follow-up

Secondary Outcome

Secondary end points are side effects, radiation toxicity and long-term effects

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Charité-Universitätsmedizin, Berlin**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2019/06/01**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **0 Years**
- Maximum Age: **17 Years**

Additional Inclusion Criteria

age < 18, diagnosis of CNS lesion, interdisciplinary consent for radiosurgical intervention, possibility of consecutive follow up controls, consent form signed by both parents (and child depending on his/her age)

Exclusion criteria

age of 18 or older, pregnancy, breast feeding

Addresses

- **Primary Sponsor**

  Charité Campus Virchow-Klinikum

Primary Sponsor

Charité Campus Virchow-Klinikum
Augustenburger Platz 1
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■ **Contact for Scientific Queries**

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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 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.*