

Trial Description

Title

Minimally invasive resection of spinal and paraspinal benign nerve sheath tumors

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Minimally invasive surgical techniques are used in increasing numbers in various surgical fields. This also applies to spinal surgery. Benign processes of the spine include nerve sheath tumors such as schwannomas and neurofibromas. The traditional surgical treatment involves microsurgical removal via open approaches. Recently, several minimally invasive techniques have been described. These minimally invasive techniques have been used regularly for the treatment of spinal tumors in the Department of Neurosurgery University Hospital Freiburg since 2007. This research project is to characterize the role of minimally invasive surgical techniques for the removal of benign nerve sheath tumors.

Brief Summary in Scientific Language

Minimally invasive surgical techniques are used in increasing numbers in various surgical fields. This also applies to spinal surgery. Benign processes of the spine include nerve sheath tumors such as schwannomas and neurofibromas. The traditional surgical treatment involves microsurgical removal via open approaches. Recently, several minimally invasive techniques have been described. These minimally invasive techniques have been used regularly for the treatment of spinal tumors in the Department of Neurosurgery University Hospital Freiburg since 2007. This research project is to characterize the role of minimally invasive surgical techniques for the removal of benign nerve sheath tumors.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00004842**
- Date of Registration in DRKS: **2013/08/19**
- 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.: **98/13 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **D36.1 - Benign neoplasm: Peripheral nerves and autonomic nervous system**
- ICD10: **D48.2 - Neoplasm of uncertain or unknown behaviour: Peripheral nerves and autonomic nervous system**

Interventions/Observational Groups

- Arm 1: **Minimally invasive resection of spinal and paraspinal benign nerve sheath tumors.**

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: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Completeness of tumor resection (postoperative MRI)

Secondary Outcome

Postoperative neurological status compared to preoperative; estimated blood loss; operative time

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center **Neurochirurgische Klinik, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/02/03**
- Target Sample Size: **13**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **99 Years**

Additional Inclusion Criteria

Operative resection of a spinal/paraspinal tumor via a minimal-invasive approach between 06/2007 and 10/2012. Verification of a schwannoma or neurofibroma.

Amendment 02/17 with extended period of retrospective inclusion (06/2007 - 10/2016).

Exclusion criteria

Verification of a malignant nerve sheath tumor.

Addresses

■ **Primary Sponsor**

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■ **Contact for Scientific Queries**

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■ **Contact for Public 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 complete, follow-up complete**
- Study Closing (LPLV): **2017/09/21**

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.*