PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Posterior decompression and fusion in patients with multi-level cervical spondylotic myelopathy

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

In cervical spinal canal stenosis, there is a narrowing (stenosis) of the bony canal in the area of the cervical spine, where the spinal cord is located. A narrowing of this channel can lead to damage to the spinal cord (myelopathy). Symptoms of myelopathy include feelings or impairments in the arms and legs, walking difficulties or problems with urination and bowel movements or sexual dysfunctions. The spinal stenosis is usually due to the advancing age of the patient (degenerative). Occasionally, the stenosis does not only occur on one single movement segment of the cervical spine (monosegmental), but affects several segments (multisegmental). In a multisegmental cervical spinal canal stenosis with appropriate clinical symptoms, a relief of the spinal cord from the neck (posterior), may be necessary with subsequent stabilization of the bony structures with a screw and rod system (spinal fusion). This procedure has been routinely performed in our department for over ten years. Nevertheless, it is a complex, several-hour intervention. Due to the necessary stabilization of the cervical spine over several movement segments, there is also a permanent restriction of movement after the operation. The aim of this research project is to retrospectively record the peri-and short-term postoperative course of treatment of patients undergoing degenerative, multisegmental cervical spinal canal stenosis by multi-level posterior spondylodesis from 2004 to 2016, as well as to collect data on long-term outcome and current findings by evaluating the patients in our out-patient clinic or by sending questionnaires or via telephone interviews.

Brief Summary in Scientific Language

If there are already significant clinical signs of spinal cord injury due to cervical spinal stenosis, surgical treatment is recommended (1,2). If there is a narrowing of the spinal canal over three or more segments, posterior decompression of the spinal cord can be performed, followed by stabilization of the bony structures via a screw-rod system (3). Alternatives to this surgical technique are e.g. laminoplasty or anterior approaches. In laminoplasty, the bony structures are reinserted after decompression and fixed for example with small metal plates and screws to avoid the use of a screw-rod system. In the anterior approach, the relief of the spinal cord is achieved via multi-level discectomies with subsequent

insertion of intervertebral placeholders (Cage) and possibly also plate / screw systems. So far, there is no agreement on the optimal treatment method in the literature (4,5).

1. Fehlings MG, Wilson JR, Yoon ST, Rhee JM, Shamji MF, Lawrence BD. Symptomatic progression of cervical myelopathy and the role of nonsurgical management: a consensus statement. Spine (Phila Pa 1976). 2013; 38: S19-S20.

2nd Karadimas SK, Erwin WM, Ely CG, Dettori JR, Fehlings MG. Pathophysiology and natural history of cervical spondylotic myelopathy. Spine (Phila Pa 1976). 2013; 38: S21-S36.

3. Cabraja M, Abbushi A, Koeppen D, Kroppenstedt S, Woiciechowsky C. Comparison between anterior and posterior decompression with instrumentation for cervical spondylotic myelopathy: sagittal alignment and clinical outcome. Neurosurgical Focus. 2010; 28: E15.

4. Lawrence BD, Jacobs WB, Norvell DC, Hermsmeyer JT, Chapman JR, Brodke DS. Anterior versus posterior approach to cervical spondylotic myelopathy treatment: a systematic review. Spine. 2013; 38: S173-S182.

5. Farrokhi MR, Ghaffarpasand F, Khani M, Gholami M. Evidence-Based Stepwise Surgical Approach to Cervical Spondylotic Myelopathy: A Narrative Review of the Current Literature. World Neurosurg. (2016) 94: 97-110.

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

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Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00014285**
- Date of Registration in DRKS: **2018/03/14**
- 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.: **465/17 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **M47.12 - [generalization M47.1: Other spondylosis with myelopathy]**

Interventions/Observational Groups

- Arm 1: **Patients ≥ 18 years with degenerative, multi-level, cervical spondylotic myelopathy surgically treated with multi-level posterior decompression and fusion over the period of 2004-2016.**
  The postoperative course of treatment is recorded retrospectively, and long-term data and current findings are collected via appointments to the outpatient clinic or by sending questionnaires or telephone interviews.

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

Major complications occuring within 30 days after posterior decompression and fusion in patients with multi-level cervical spondylotic myelopathy: death, myocardial infarction, vertebral artery injury, insult, pulmonary embolism, severe pneumonia with respiratory care, reoperation, new motor deficit KG ≤ 3/5.
Incidence of complications in the further postoperative course (e.g., revision surgery).
The postoperative complications are retrospectively collected from medical records.
Current Cervical Spine Disorders / Pain on the numeric rating scale (NRS). The current complaints are collected in the outpatient clinic or via questionnaires or telephone interviews.
Objective measurement of parameters of cervical spine mobility (inclination, reclination, lateral tilt, and rotation).
For the objective measurement, a non-invasive measuring device (CROM3, Performance Attainment Associates), which has already been validated in several studies, is used.

Secondary Outcome

Minor complications occurring within 30 days after posterior decompression and fusion in patients with multi-level cervical spondylotic myelopathy: new motor deficit KG> 3/5, mild pneumonia with transient oxygen demand, postoperative confusion, urinary tract infection, transfusion-dependent anemia, deep vein thrombosis, hepatic insufficiency, dural lesion / CSF fistula.
The postoperative complications are retrospectively collected from medical records.
Subjective restriction of movement, information on quality of life and impairment in everyday life (e.g. driving), patient satisfaction.
The current complaints are collected in the outpatient clinic or via questionnaires or telephone interviews.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Neurochirurgie, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/01/01**
- Target Sample Size: **100**
- 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

Patients ≥ 18 years with multi-level cervical spondylotic myelopathy treated surgically with multi-level posterior decompression and fusion over the period 2004-2016.

Exclusion criteria

Patients <18 years.
For measurement of cervical range of motion in outpatient examination: Uncooperative patients; Patients who can not sit on an examination chair due to other physical limitations; Patient with pacemaker and defibrillator.

Addresses

- **Primary Sponsor**

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  Fax: **[---]***
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Sources of Monetary or Material Support

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

  Klinik für Neurochirurgie Universitätsklinikum Freiburg

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.*