# Trial Description

## Title

**Objective and subjective changes of neck motion after anterior and posterior procedures in the cervical spine with particular focus on patient age**

## Trial Acronym

**[---]***

## URL of the trial

**[---]***

## Brief Summary in Lay Language

**Operations on the cervical spine are comparatively frequent. Due to the aging population, the number of operations will further increase. Operations are performed because of varying reasons, e.g. radiculopathy due to cervical herniated discs, narrowing of the vertebral canal or other degenerative changes. In many cases, a fusion of the affected motion segments is performed. Patients often ask whether and how strongly they are restricted in their mobility after the operation, and whether they will be able to perform everyday duties, e.g. driving (shoulder sight). The aim of this study is to determine the objective and subjective change in motility after cervical surgery within the usual postoperative controls after 6 to 12 weeks and after one year and to compare these findings with the preoperative examination. For the objective measurement, a non-invasive instrument (CROM3, Performance Attainment Associates), which is already validated in several studies, is used. This is placed on the head and measures the inclination / reclination, lateral inclination and rotation in the area of the cervical spine via several inclinometers and a compass-magnet device. The subjective movement restriction is assessed via a questionnaire. With the resulting data, findings on the biodynamics of the cervical spine are to be obtained. Furthermore, clinicians should be able to better advise patients in the future on the change in mobility to be expected in dependence of the operated movement segments. Due to the increasing degenerative changes in age, a stronger objective and subjective postoperative change in mobility is to be expected in younger patients than in the elderly.**

## Brief Summary in Scientific Language

**Some studies have already investigated the objective change of mobility after an anterior operation on the cervical spine with the CROM device (1-5). These studies, however, are limited in their significance, partly due to their lack of consideration of the subjective restriction and restriction in daily activities (2-5) and partly due to a short follow-up period of only 3 months (4) or 6 months (1). Also, we regard the number of patients examined in these studies as too low (1). Exact results on the objective and subjective restriction of posterior fusion techniques are not available. Furthermore, no data are available on older patient groups, which are likely to be less restricted than younger patients due to their degenerative changes following a fusion operation.**

**1. Landers MR, Addis KA, Longhurst JK, Vom Steeg B, Puentedura EJ, Daubs MD. Anterior cervical decompression and fusion on neck range of motion, pain, and function: a prospective analysis. Spine J Off J North Am Spine Soc. 2013 Nov; 13(11):1650–8.**

**2. Wu X-D, Wang X-W, Yuan W, Liu Y, Tsai N, Peng Y-C, et al. The effect of multilevel anterior cervical fusion on neck motion. Eur Spine J Off Publ Eur Spine Soc Eur Spinal Deform Soc Eur Sect Cerv Spine Res Soc. 2012 Jul;21(7):1368–73.**

**3. Wu X-D, Yuan W, Chen H-J, Chen Y, Wang J-X, Cao P, et al. Neck motion following multilevel anterior cervical fusion: comparison of short-term and midterm results. J Neurosurg Spine. 2013 Apr;18(4):362–6.**

**4. Hilibrand AS, Balasubramanian K, Eichenbaum M, Thinnes JH, Daffner S, Berta S, et al. The effect of anterior cervical fusion on neck motion. Spine. 2006 Jul 1;31(15):1688–92.**

**5. Chen Y, Yuan W, Wu X, Chen H, Wang X, Yang L, et al. The effect of range of motion after single-level discover cervical artificial disk replacement. J Spinal Disord Tech. 2013 Jul;26(5):E158-162.**

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

**[---]***

**Description IPD sharing plan**

**[---]***

## Organizational Data

- DRKS-ID: **DRKS00011277**
- Date of Registration in DRKS: **2016/11/29**
- 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.: **485/16 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **M43.20 - [generalization M43.2: Other fusion of spine]**

## Interventions/Observational Groups

- Arm 1: **Adult patients with a degenerative cervical pathology who are to be treated via an anterior approach (decompression and fusion or prosthesis) or a dorsal approach (decompression without or with fusion). The aim of this study is to determine the objective and subjective change in motility after cervical surgery within the usual postoperative controls after 6 to 12 weeks and after one year and to compare these findings with the preoperative examination. For the objective measurement, a non-invasive instrument (CROM3, Performance Attainment Associates), which is already validated in several studies, is used. This is placed on the head and measures the inclination / reclination, lateral inclination and rotation in the area of the cervical spine via several inclinometers and a compass-magnet device. The subjective movement restriction is assessed via a questionnaire.**

## Characteristics

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

### Primary Outcome

**Objective change of mobility after surgery on the cervical spine one year after surgery compared to the preoperative findings.
For the objective measurement, a non-invasive instrument (CROM3, Performance Attainment Associates), which is already validated in several studies, is used. This is placed on the head and measures the inclination / reclination, lateral inclination and rotation in the area of the cervical spine via several inclinometers and a compass-magnet device.**

### Secondary Outcome

**Objective change of mobility after surgery on the cervical spine 6 to 12 weeks after surgery compared to the preoperative findings; Subjective impairment of movement, quality of life and impairment in everyday duties, patient satisfaction, pain on numerical rating scale (NRS) 6 - 12 weeks and one year after surgery.**

## 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: **2016/12/05**
- Target Sample Size: **250**
- 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

**Adult patients with a degenerative cervical pathology who are to be treated via an anterior approach (decompression and fusion or prosthesis) or a dorsal approach (decompression without or with fusion).**

### Exclusion criteria

**Patients with preoperative instability and necessity of immobilization; Uncooperative patients; Patients who are not able to sit on the examination chair due to other physical limitations; Patients with a pacemaker and defibrillator (the CROM3 device uses a magnet).**

## Addresses

- **Primary Sponsor**

  **Universitätsklinikum Freiburg**
  **Hugstetter Strasse 49**

**Primary Sponsor**

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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.*