Trial Description

Title

Navigated posterior C1/C2 spondylodesis in the elderly (> 70 years)

Trial Acronym

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URL of the trial

[---]*

Brief Summary in Lay Language

In patients with pain or neurological deficits because of pathologies of the dens axis a C1/C2 (respectively C3) spondylodesis is possible when conservative treatment fails. According to the kind of lesion and the individual anatomy anterior or posterior approaches are used. By now, these procedures can be performed in a minimally-invasive manner and by use of neuronavigation for exact screw placement. Still, these procedures are complex and lethal complications can occure (e.g. injury of the vertebral artery). Often elderly patients are affected by lesions of C2 with a respecitvely higher rate of comorbidities. In some of the elderly patients even a malignant diseases is already present with a reduced life expectancy. In these cases the spondylodesis is undertaken to help the patients spend the rest of their lifes in a good quality and without pain. The literature for navigated posterior spondylodesis of complex cervical pathologies in elderly patients is limited. No study uses intraoperative navigation for screw placement.

Brief Summary in Scientific Language

In several studies the posterior C1/C2 spondylodesis in the elderly was investigated. Frangen et al. examined 27 patients with however only acute fractures and with patient age of already 63 years (1). Chen et al. reviewed patients starting at 65 years, however with a mixed patient collective of anterior and posterior procedures (2). The same limitations are present in the study of Omeis et al., who reviewed patients over 70 years, but 16 of 29 patients were treated bei anterior spondylodesis (3). Kaminski et al. analyzed a homogenous patient cohort (all patients > 70 years, all patients treated by posterior spondylodesis), but the screws were not placed by using neuronavigation (4).

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Organizational Data

- DRKS-ID: **DRKS00009412**
- Date of Registration in DRKS: **2015/09/23**
- 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.: **393/15 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **M53.21 - [generalization M53.2: Spinal instabilities]**
- ICD10: **S12.1 - Fracture of second cervical vertebra**

Interventions/Observational Groups

- Arm 1: **Patients ≥ 70 years with a pathology of C2, who were treated with navigated posterior C1/C2 (respectively C3) spondylodesis between 2008 and 02/2015. Retrospectively the incidence of major- and minor-complications within 30 days after surgery, patient satisfaction, VAS and location of the screws will be aquired.**

Characteristics

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

Primary Outcome

Major-complications within 30 days after C1/C2 spondylodesis: death, myocardial infarction, vertebral artery injury, stroke, pulmonary embolism, severe pneumonia with intubation, reoperation, new motor deficit level ≤ 3/5.

Secondary Outcome

Minor-complications within 30 days after C1/C2 spondylodesis: new motor deficit level > 3/5, mild pneumonie with transient oxygen application, postoperative confusion, urinary tract infection, anemia requiring transfusions, deep vein thrombosis, liver insufficiency, dural lesion/cerebrospinal fluid fistula. Patient satisfaction, VAS, location of the screws.

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: **2015/09/28**
- Target Sample Size: **30**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **70 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Patients ≥ 70 years with a pathology of C2, who were treated by navigated posterior C1/C2 (respectively C3) spondylodesis between 2008 and 02/2015.

Exclusion criteria

Patients < 70 years. Occipitocervical spondylodesis, spondylodesis further than C3, non-navigated spondylodesis.

Addresses

- **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 complete, follow-up complete**
- Study Closing (LPLV): **2016/03/31**

Trial Publications, Results and other documents

- Abstract **Abstract Pubmed**

** 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.*