Trial Description

Title

Minimally invasive transforaminal lumbar interbody fusion (MIS TLIF): perioperative and postoperative complications in patients aged 80 and older

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

As part of a stabilization of the lumbar spine, screws are introduced through a bony bridge (pedicle) into the vertebral body; furthermore, a spacer (cage) is introduced into the intervertebral disc space to ensure sufficient stability in spinal segments with instability or degenerative disease. The minimally invasive technique called transforaminal lumbar interbody fusion (MIS TLIF) offers advantages compared to the open technique such as smaller incisions, less muscle trauma, less frequent wound complications, less blood loss during surgery, earlier mobilization and earlier discharge from hospital. For this surgical technique, the evidence regarding the perioperative and postoperative complications in older patients is very limited. Available studies stated no significantly increased risk in patients over 65 or 70 years. The proportion of patients with an age of at least 80 years, however, was low in these studies. Data regarding the perioperative and postoperative complications after MIS TLIF for patients with an age of at least 80 years is not available.
The aim of this research project is the retrospective investigation of perioperative and postoperative complications in patients with an age of at least 80 years after lumbar interbody fusion minimally invasive (MIS TLIF).

Brief Summary in Scientific Language

As part of a stabilization of the lumbar spine, transpedicular screws are introduced into the vertebral body, and a cage is introduced into the intervertebral disc space to ensure sufficient stability in spinal segments with instability or degenerative disease. The minimally invasive technique called transforaminal lumbar interbody fusion (MIS TLIF) offers advantages compared to the open technique such as smaller incisions, less muscle trauma, less frequent wound complications, less blood loss during surgery, earlier mobilization and earlier discharge from hospital. For this surgical technique, the evidence regarding the perioperative and postoperative complications in older patients is very limited. Available studies stated no significantly increased risk in patients over 65 or 70 years. The proportion of patients with an age of at least 80 years, however, was low in these studies. Data regarding the perioperative and postoperative complications after MIS TLIF for patients with an age of at least 80 years is not available.
The aim of this research project is the retrospective investigation of perioperative and postoperative complications in patients with an age of at least 80 years after

lumbar interbody fusion minimally invasive (MIS TLIF).

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

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00007997**
- Date of Registration in DRKS: **2015/04/08**
- 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.: **128/15 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **M53.26 - [generalization M53.2: Spinal instabilities]**
- ICD10: **M43.16 - [generalization M43.1: Spondylolisthesis]**

Interventions/Observational Groups

- Arm 1: **Assessment of perioperative and postoperative complications in patients ≥ 80 years who underwent MIS TLIF between March 2009 and February 2014 due to lumbar instability or degeneration.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***

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

Occurrence of major complications within 30 days of MIS TLIF: death, myocardial infarction, stroke, pulmonary embolism, severe pneumonia / mechanical ventilation, reoperation, new motor deficit grade ≤ 3/5.

Secondary Outcome

Occurrence of minor complications within 30 days of MIS TLIF: new motor deficit grade > 3/5, slight pneumonia / transient dependency on oxygen, postoperative confusion, urinary tract infection, anemia requiring transfusion, deep vein thrombosis, intraoperative durotomy, hepatic impairment, depressive episode, sacroiliac joint syndrome.

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: **2015/04/06**
- Target Sample Size: **20**
- Monocenter/Multicenter trial: **Monocenter trial**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2015/04/06**

Target Sample Size: **20**

Monocenter/Multicenter trial: **Monocenter trial**

- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **80 Years**
- Maximum Age: **90 Years**

Additional Inclusion Criteria

Patients ≥ 80 years who underwent MIS TLIF between March 2009 and February 2014 due to lumbar instability or degeneration.

Exclusion criteria

Patient age < 80 years. MIS TLIF due to infection or trauma.

Addresses

- **Primary Sponsor**

Universitätsklinikum Freiburg
Hugstetter Strasse 49
79095 Freiburg
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.uniklinik-freiburg.de**

- **Contact for Scientific Queries**

Neurochirurgische Universitätsklinik Freiburg
Mr. Dr. med. Jan-Helge Klingler
Breisacher Str. 64
79106 Freiburg
Germany

Telephone: **+49 761 270 50010**

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Neurochirurgische Universitätsklinik Freiburg
Mr. Dr. med. Jan-Helge Klingler
Breisacher Str. 64
79106 Freiburg
Germany

Telephone: **+49 761 270 50010**
Fax: **+49 761 270 50080**
E-mail: **jan-helge.klingler at uniklinik-freiburg.de**
URL: **http://www.uniklinik-freiburg.de/neurochirurgie/live/index.html**

- **Contact for Public Queries**

Neurochirurgische Universitätsklinik Freiburg
Mr. Dr. med. Jan-Helge Klingler
Breisacher Str. 64
79106 Freiburg
Germany

Telephone: **+49 761 270 50010**
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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): **2016/07/15**

Trial Publications, Results and other documents

- Paper **PubMed - Abstract**

** 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.*