DRKS-ID: **DRKS00010843**
Date of Registration in DRKS: **2016/08/15**
Date of Registration in Partner Registry or other Primary Registry: **[---]***

Deutsches Register Klinischer Studien
German Clinical Trials Register

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

Trial Description

Title

Navigation-guided and 3D-imaging controlled minimally invasive posterior instrumentation in patients with pyogenic thoracolumbar spondylodiscitis

Trial Acronym

Spondylodiscitis

URL of the trial

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Brief Summary in Lay Language

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Brief Summary in Scientific Language

Pyogenic spondylodiscitis is an infectious disease of the spine with an incidence of around 1: 250.000. The disease can either be caused by a bacterial (such as Staphylococci, Salmonella, Neisseria, Brucella), mycotic, viral or a parasitic spread (usually haematogenic), or by a iatrogenic infection following previous operation. In many cases, however, the infectious agent cannot be detected (Spondylitis fungax). A pyogenic spondylodiscitis is present as soon as both, the intervertebral disc and the adjacent vertebral bodies, are affected by infectious formations, and it thus occurs mainly in the anterior parts of the spine.
The course of spondylodiscitis is variable and can range from no clinical signs to sepsis or neurological deficits due to epidural abscesses. Bacterial invasion of the intervertebral disc and destruction of the adjacent bony structures frequently leads to pronounced local pain and immobilization of the patients.
The treatment depends on factors such as localization of the infection, grade of osseous destruction, neurological deficits and general symptoms. A conservative treatment with antibiotic agents and immobilization for several weeks is traditionally recommended in the early stage of the disease.
Indications for operative treatment are significant neurological deficits caused by compression of the spinal cord or the cauda equina, spinal instability, progressive bony destruction/ deformity, or progressive pain after conservative therapy. Furthermore, surgical treatment should also be considered in patients with therapy-refractory pain, particularly in elderly patients, since longer periods of immobilization can cause thromboembolic complications and muscle wasting. The optimal treatment of the patient should thus be minimally incriminating, effectively restore the stability of the spine, and allow for fast pain reduction and ambulation. A sole minimal invasive instrumentation of the thoracolumbar spine using a percutaneous/ transmuscular pedicle screw and rod system meets these criteria and might be an effective and safe alternative to the traditional invasive operation methods.

The aim of this study is to show that a minimally invasive instrumentation can effectively restore the stability of the thoracolumbar spine and avoid kyphotic deformity. In combination with standard antibiotic treatment this surgical procedure should be sufficient to cure the infection.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00010843**
- Date of Registration in DRKS: **2016/08/15**
- 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.: **191/15 , Ethik-Kommission des Fachbereichs Medizin der Justus-Liebig-Universität Gießen**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1185-4994**

Health condition or Problem studied

- ICD10: **M46.4 - Discitis, unspecified**

Interventions/Observational Groups

- Arm 1: **We want to prospectively examine 25 patients, that we will operate with the described minimally invasive technique (A minimal invasive instrumentation of the thoracolumbar spine using a percutaneous/ transmuscular pedicle screw and rod system from behind).**

  Perioperative laboratory and radiological data as well as intraoperative data will be collected during the hospital course. Pre- and postoperative clinical data collection will be supplemented by a questionnaire that incorporates the Charlson Comorbidity Index, the Oswestry Disability Index, the Visual Analogue Scale, and the EuroQol EQ-5D score.
  During follow-up visits at 6 weeks, 6 months, and 12 months clinical data will again be collected with help of the questionnaire, and the status of the

instrumentation, the sagittal profile of the spine, as well as the formation of bridging bony spurs will be assessed by X-ray or CT scans, according to the standard of the respective study center.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- 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

Primary endpoint: Difference (vs. preoperative) Oswestry Disability Index (ODI) at 6 months

Secondary Outcome

Secondary endpoints: Pain and disability postoperative, at 6 weeks, 6 months, and 12 months (ODI; Visual Analogue Scale/ VAS; Macnab criteria), quality of life (EQ-5D-3L), time to mobilization, laboratory values (leukocytes, CRP), screw misplacement (Gertzbein/ Robbins), intra-/perioperative complications, reoperations, sagittal profile angles, formation of bridging bony spurs.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätsklinikum Gießen und Marburg, Standort Gießen**
- University Medical Center **Würzburg**
- University Medical Center **Mainz**

- University Medical Center **Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/04/19**
- Target Sample Size: **50**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Subjects with the indication for operative treatment of pyogenic thoracolumbar spondylodiscitis (minimally invasive posterior instrumentation +/- decompression +/- vertebral body biopsy; navigation-guidance/3D-imaging).

Exclusion criteria

•Patient not suitable for anaesthesia
•Treatment with any other (surgical or conservative) procedure
•Incomplete data
•No study consent

Addresses

- **Primary Sponsor**

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URL: **http://www.ukgm.de/ugm_2/deu/ugi_nch/index.html**

- **Contact for Scientific Queries**

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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Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Background literature **Gatt ME, Paltiel O, Bursztyn M (2004) Is prolonged immobilization a risk factor for symptomatic venous thromboembolism in elderly bedridden patients? Results of a historical-cohort study. Thromb Haemost 91:538–543.**
- Background literature **Hadjipavlou AG, Mader JT, Necessary JT, Muffoletto AJ (2000) Hematogenous pyogenic spinal infections and their surgical management. Spine 25:1668–1679.**
- Background literature **McHenry MC, Easley KA, Locker GA (2002) Vertebral osteomyelitis: long-term outcome of 253 patients from 7 Cleveland area hospitals. Clin Infect Dis 34:1342–1350.**
- Background literature **Prandoni P, Villalta S, Tormene D, Spiezia L, Pesavento R (2007) Immobilization resulting from chronic medical diseases: a new risk factor for recurrent venous thromboembolism in anticoagulated patients. J Thromb Haemost 5:1786–1787.**
- Background literature **Safran O, Rand N, Kaplan L, Sagiv S, Floman Y (1998) Sequential or simultaneous, same-day anterior decompression and posterior stabilization in the management of vertebral osteomyelitis of the lumbar spine. Spine 23:1885–1890.**
- Background literature **Sapico FL, Montgomerie JZ (1979) Pyogenic vertebral osteomyelitis: report of nine cases and review of the literature. Rev Infect Dis 1:754–776.**
- Background literature **Wisneski RJ (1991) Infectious disease of the spine. Diagnostic and treatment considerations. Orthop Clin North Am 22:491–501.**
- Further trial documents **Studienprotokoll**

** 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.*