Trial Description

Title

Randomized clinical trial to prove the effectiveness of a spine orthosis (Spinova Support Plus by Bauerfeind) for the postoperative treatment after lumbar spinal fusion of one or two segments in L3-S1 due to degenerative lumbar spine desease

Trial Acronym

AWB/Spinova-01

URL of the trial

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Brief Summary in Lay Language

Before doing a fusion of the lower lumbar spine, patients are classified into two groups by chance. One group receives a spine orthosis (Spinova Support Plus by Bauerfeind) after surgery for supporting the rehabilition, the other one doesn't. During rehabilitation the clinical outcome is measured by questionaires and the endurance of the back muscles is measured by a surface elektromyogramm.

Brief Summary in Scientific Language

This is a randoized clinical trial for the postoperative treatment after lumbar spinal fusion of one or two segments in L3-S1 due to degenerative lumbar spine desease. One group receives a spine orthosis (Spinova Support Plus by Bauerfeind), the other one doesn't. In both groups the clinical outcome is measured by questionaires (Oswestry Disability Index, VAS, patient satisfaction). In addition an surface electromyogramm is done for diagnosing the fatigue index of the erector spinae.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00006865**
- Date of Registration in DRKS: **2014/10/13**

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- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **381/13 , Ethik-Kommission der Medizinischen Fakultät der Rheinischen Friedrich-Wilhelms-Universität Bonn**

Secondary IDs

Health condition or Problem studied

- ICD10: **M53.26 - [generalization M53.2: Spinal instabilities]**
- ICD10: **M42.16 - [generalization M42.1: Adult osteochondrosis of spine]**
- ICD10: **M43.16 - [generalization M43.1: Spondylolisthesis]**
- ICD10: **M47.86 - [generalization M47.8: Other spondylosis]**
- ICD10: **M48.06 - [generalization M48.0: Spinal stenosis]**

Interventions/Observational Groups

- Arm 1: **Additional to the standard postoperative treatment, patients receive a spinal orthosis (Spinova Support Plus by Bauerfeind) for 12 weeks after surgery. After 6 weeks the bridging pad of the orthesis is removed.**
- Arm 2: **The patients receive standard postoperative treatment after surgery without orthosis.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Supportive care**

Study Type: **Interventional**

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

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Active control**

Purpose: **Supportive care**

- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary aim is to prove the additional benefit of a spine othosis after lumbar fusion.
To demonstrate the difference in the postoperative treatment, all patients of both groups receive questionaires about their aktivities of daily living (Oswestry Disability Index), about pain (visual analogue scale) and about the satisfaction (very satisfied, satisfied, largely satisfied, partially satisfied, rarely satisfied, not satisfied) before surgery and at the time of discharge. Patients receive further questionaires 6 weeks, 12 weeks, 6 months and 12 months after surgery.

Secondary Outcome

Secondary aim is to show a better endurance of the erector spinae in the group of patients, who receive a spinal orthosis.
To prove that assumption, the muscle fatigue index is derived fom a surface EMG of the erector spinae at all patients of both groups before surgery and at the time of discharge, 6 weeks and 12 weeks after surgery.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Orthopädie und Unfallchirurgie, Bonn**

Recruitment

- Planned/Actual: **Planned**

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- (Anticipated or Actual) Date of First Enrollment: **2014/10/10**
- Target Sample Size: **50**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **25 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Patients after lumbar spinal fusion of one or two segments in L3-S1 due to degenerative lumbar spine desease

Exclusion criteria

Age <25; Patients, who cannot give their consent; breast feeding, pregnant women or women, who plan to get pregnat during the clinical trail; Patients with walking disability due to osteoarthritis III° and more; systemic neurological desease with limited mobility, e.g. Parkinson's desease or multiple sclerosis; Patients with intolerance or known limitations, that make the participation of the clinical trial impossible.

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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  Mr. Dr. Yorck Rommelspacher

Contact for Scientific Queries

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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

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.*