Trial Description

Title

Upright magnetic resonance imaging for evaluation of lateral recess stenosis of the lumbar spine

Trial Acronym

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URL of the trial

[---]*

Brief Summary in Lay Language

Leg pain (sciatica) caused by a pathology of the lumbar spine is a common medical condition. Usually nerval root compression due to disk herniation or lateral recess stenosis is the underlying pathology. Standard imaging technique is MRI in supine position. Some patients report substantial increase of leg pain in upright position, thus under axial load of the spine. In these cases a standard supine MRI may not detect a relevant lateral recess stenosis. Gold standard for imaging under axial loading today is myelography (injection of contrast medium in the spinal canal followed by several radiographs in different positions). The technique of a movable MRI scanner for image accquisition in upright position may offer an alternative for these cases. Absence of invasiveness and X-ray exposure are advantages of MRI compared to myelography. Aim of the study is to compare the upright MRI in patients with suspected lateral recess stenosis, that are scheduled for myelography. Images of the upright MRI will be compared to the images of the myelography and standard MRI in supine position.

Brief Summary in Scientific Language

The objective of this research project is to evaluate lateral recess stenosis using a dedicated upright MRI scanner. Twenty patients with lumbar radiculopathy but inconclusive supine MRI scan are to be included. As mentioned above, this subgroup of patients is typically scheduled for conventional myelography to disclose the causative nerve root compression. Within the study, these patients additionally undergo an upright MRI scan, which will be compared to conventional myelography to assess the diagnostic value of upright MRI scans for detecting the causative nerve root compression.
Furthermore, the image data set of the upright MRI scanner will be compared to a standardized supine MRI scan acquired in a conventional MRI device in supine position to assess image quality of the upright scanner.
If upright MRI will promise to be a useful tool for the diagnosis of nerve root compression caused by lateral recess stenosis, it may completely replace conventional myelography for the diagnosis of this disease in the future, hereby avoiding complications of this invasive procedure.

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: **DRKS00013292**
- Date of Registration in DRKS: **2017/11/10**
- 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.: **432/17 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **M48.06 - [generalization M48.0: Spinal stenosis]**
- ICD10: **M54.3 - Sciatica**

Interventions/Observational Groups

- Arm 1: **Upright MRI in an open, tilting MRI scanner (Esaote G-scan). The upright MRI will be performed after standard MRI in supine position and before the scheduled myelography.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***

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

- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

A) Extent of lateral recess stenosis
Measurement of the lateral recess in axial MRI slices in anterior-posterior direction. Soft tissue or bony edges are defined as borders. Measurements in the relevant nerve root level are performed in all slices depicting the affected nerve root in the lateral recess. Measurements are performed in the standard MRI in supine position, in the upright MRI and in the myelography respectively.
B) Quantitative evaluation of contrast and signal to noise ratio in the Upright MRI. Qualitative evaluation of image quality using a 4-grade scale. Image evaluation is performed by two experienced neuroradiologists.

Secondary Outcome

none

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Universitätsklinikum Freiburg, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/11/13**
- Target Sample Size: **20**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **90 Years**

Additional Inclusion Criteria

- Leg pain, aggravating under axial loading (in upright position e.g. standing, walking)
- inconclusive standard MRI in supine position and therefor indication for conventional myelographie

Exclusion criteria

Absent indication for conventional myelography;
S.p. lumbar spondylodesis; Contraindication for MRI: (cardiac pace maker, defibrillator, LVAD-device cochlea implant, ferromagnetic material); BMI>30kg/m2; claustrophobia

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Private sponsorship (foundations, study societies, etc.)**

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URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **2021/04/19**
- Number of Participants in Germany after Recruiting complete: **10**
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **10**

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.*