Trial Description

Title

Radiation exposure to the surgeon and patient during kyphoplasty

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The increasing life expectancy as well as improved therapy possibilities with tumor patients and therefore longer illness course lead increasingly to requiring treatment osteoporotic or tumour-conditioned vertebral body compression fractures. In such process represents the Kyphoplasty a minimally invasive therapy procedure, in which the bone cement is injected into the fractured vertebral body. This leads to an improvement in stability and immediate pain relief. In the case of kyphoplasty, the intraoperative use of ionizing radiation is required in order to insertion the instrumentarium in a controlled manner, to monitor the cement injection and thus to avoid an undesirable cement leakage. Dosimetry data for the intraoperative radiation exposure of the surgeon and the patient are hardly available. The aim of this research project is to obtain meaningful dosimetric data regarding the radiation exposure of the surgeon and the patient during kyphoplasty. Based on these data, a radiation-conserving surgical technique is to be developed. All therapeutic measures within the study correspond to our clinical routine.

Brief Summary in Scientific Language

Dosimetry data for the intraoperative radiation exposure of the surgeon and the patient are hardly available. Often only exposure times are reported with values up to 27.7 min per vertebroplasty. According to the publication by Fitousi et al. and the recommendations of the International Commission on Radiological Protection (ICRP) for occupationally exposed persons (category B), the annual dose limit for the ocular lens has already been reached after 30 vertebroplasty. On the other hand, our own retrospective data present exposure times of less than 60 seconds / kyphoplasty with conserving use of ionizing radiation. The aim of this study is to obtain meaningful dosimetric data regarding the radiation exposure of the surgeon and the patient during kyphoplasty. Based on these data, a radiation-conserving surgical technique is to be developed.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00011908**
- Date of Registration in DRKS: **2017/05/16**
- 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.: **64/17 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **T08.0 - [generalization T08: Fracture of spine, level unspecified]**
- Free text: **Radiation exposureto te surgeon und patient during kyphoplasty**

Interventions/Observational Groups

- Arm 1: **Course of the study:**
  -Recruiting patients via the neurosurgery outpatient department and assignment of peripheral assigners.
  -Check the inclusion / exclusion criteria
  -Inclusion of a total of 40 patients for mono- / bivertebral kyphoplasty into the study
  -Perform of the operation (there is no additional risk for the patient because all therapeutic measures correspond to the clinical routine) with the addition of dosimeters to the surgeon and the patient. During surgery, the surgeon is protected by the use of ionizing radiation by means of lead aprons.
  -Dosimetric evaluation at Helmholtz Zentrum München
  -Statistical evaluation of results and publication

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**

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- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Radiation exposure of the surgeon and patient during mono- / bivertebral kyphoplasty on the thoracolumbar spine, measured using dosimeters at the surgeon and the patient

Secondary Outcome

exposure time, dose area product, body mass index, duration of operation, intraoperative / in-patient complications, change in pain((Visual analog scale, VAS, on the 1st postoperative day versus preoperative)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

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

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2017/05/22**
- Target Sample Size: **40**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

Indication for thoracolumbar mono- / bivertebral kyphoplasty (osteoporotic, tumorbedingt, traumatic). minimum Age 18 jears

Exclusion criteria

Indication for kyphoplasty with concomitant spine instrumentation or decompression. No Patient agreement .

Addresses

- **Primary Sponsor**

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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 planned**
- 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.*