

**Trial Description****Title**

**Incidence of Vertebral Metastasis in Patients with suspected Osteoporotic Spine Fractures**

**Trial Acronym**

[---]\*

**URL of the trial**

[---]\*

**Brief Summary in Lay Language**

**Osteoporosis is one of the most common diseases. Vertebral fractures are a common complication. The treatment of vertebral fractures in patients with osteoporosis consists under certain circumstances of the infusion of bone cement into the vertebral body (Kyphoplasty/Vertebroplasty). In some cases, the cause of the fracture is, however, a metastasis of a malignant disease. Such metastases may also damage the bone structure and can cause a fracture. To differentiate between an osteoporotic fracture and a malignant fracture based on the radiological findings is not always safe. For the planning of further therapy, the distinction is essential. There are yet no reliable data of the incidence of metastases in patients with suspected osteoporotic fractures. The knowledge of this incidence is crucial for the planning of standard operation procedures in patients with suspected osteoporotic spine fractures. This study is to determine the incidence of vertebral metastases in patients with suspected osteoporotic fractures on the basis of histological studies.**

**Brief Summary in Scientific Language**

**The incidence of metastases in patients with suspected vertebral is not yet sufficiently explored. Two prospective single-centre studies have investigated the incidence of malignant diseases in patients who underwent a kyphoplasty and vertebroplasty. In 1.3% and 2.8% multiple myeloma and low grade B-cell lymphomas were found. These patients could be applied to further diagnostic and therapy. Both studies' authors recommend routine histological examination of bone tissue in patients who undergo a kyphoplasty and vertebroplasty. An own survey of spine surgeons in Germany showed that this approach, however, is been conducted in individual cases only. The reasons are mainly in the lack of reliable data from prospective multicenter studies that reflect the situation in Europe. The planned study will be conducted as a prospective multicenter study in Germany. When performing a vertebroplasty or kyphoplasty, bone tissue from any affected vertebral should be taken for histological examination.**

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

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## Description IPD sharing plan

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00003578**
- Date of Registration in DRKS: **2012/03/29**
- 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.: **077/12-05032012 , Ethikkommission an der Medizinischen Fakultät der Universität Leipzig**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **M84.48 - [generalization M84.4: Pathological fracture, not elsewhere classified]**
- ICD10: **M80.08 - [generalization M80.0: Postmenopausal osteoporosis with pathological fracture]**

## Interventions/Observational Groups

- Arm 1: **In patients with a suspected osteoporotic fracture is which a kyphoplasty or vertebroplasty is carried out tissue for histological examination should be collected.**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Epidemiological study**
- Allocation: **Single arm study**
- Blinding: **Open (masking not used)**
- Who is blinded: [---]\*
- Control: **Uncontrolled/Single arm**
- Purpose: **Screening**
- Assignment: **Single (group)**



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Who is blinded: [---]\*

Control: **Uncontrolled/Single arm**

Purpose: **Screening**

Assignment: **Single (group)**

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

### Primary Outcome

**To Determine the incidence of vertebral metastases in patients with suspected osteoporotic fractures on the basis of histological studies.**

### Secondary Outcome

none

### Countries of recruitment

- **DE Germany**

### Locations of Recruitment

- University Medical Center **Klinik für Unfallchirurgie, Leipzig**
- Medical Center **Berufsgenossenschaftliche Unfallklinik Murnau, Wirbelsäulenchirurgie, Murnau**
- Medical Center **Heliosklinikum Borna, Klinik für Orthopädische Chirurgie, Unfall- und Handchirurgie, Interdisziplinäres Zentrum für Wirbelsäulenchirurgie, Borna**
- Medical Center **Leopoldina Krankenhaus Schweinfurt, Klinik für Spezielle Wirbelsäulenchirurgie, Schweinfurt**
- Medical Center **Klinikum Traunstein, Abteilung für Unfallchirurgie und Orthopädische Chirurgie, Traunstein**
- Medical Center **Berufsgenossenschaftliche Unfallklinik Tübingen, Klinik für Unfall- und Wiederherstellungschirurgie, Tübingen**
- University Medical Center **Universitätsklinikum Aachen, Abteilung für Unfallchirurgie, Sektion Wirbelsäulenchirurgie, Aachen**



- Medical Center **Klinikum Radebeul, Klinik für Unfallchirurgie und Orthopädie, Abteilung Wirbelsäulenchirurgie, Radebeul**
- Medical Center **Zentrum für Unfallchirurgie und Orthopädie, Abteilung der Berufsgenossenschaftlichen Unfallklinik Duisburg im Stiftungsklinikum Mittelrhein, Koblenz**
- University Medical Center **Universitätsklinik Schleswig-Holstein, Campus Kiel, Klinik für Unfallchirurgie, Kiel**
- Medical Center **Klinikum Memmingen, Klinik für Unfallchirurgie, Wiederherstellende Chirurgie und Orthopädie, Memmingen**

## Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2012/04/01**
- Target Sample Size: **700**
- 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

**Patients with vertebral fractures in which there is suspicion of an osteoporotic fracture should be included. Inclusion criterion is the indication for kyphoplasty, vertebroplasty or cement-augmented dorsal fusion provided by the attending surgeon.**

## Exclusion criteria

**Health condition that makes surgery impossible. A suspicion of vertebral metastasis based on radiological findings.**

## Addresses

- **Primary Sponsor**  
**Universitätsklinikum Leipzig**  
**Liebigstr. 18**  
**04103 Leipzig**  
**Germany**



### **Primary Sponsor**

**Universitätsklinikum Leipzig  
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#### ■ **Contact for Scientific Queries**

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## **Sources of Monetary or Material Support**

#### ■ **Institutional budget, no external funding (budget of sponsor/PI)**

**Universitätsklinikum Leipzig  
Liebigstr. 18  
04103 Leipzig  
Germany**

Telephone: [---]\*



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**Institutional budget, no external funding (budget of sponsor/PI)**

**Universitätsklinikum Leipzig**

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**04103 Leipzig**

**Germany**

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Fax: [---]\*

E-mail: [---]\*

URL: **www.uniklinikum-leipzig.de**

## 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.