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

Trial Description

Title

Prospective Evaluation of Sacrum fractures in the Elderly

Trial Acronym

PRESS

URL of the trial

http:///

Brief Summary in Lay Language

Patients over 60 years or under 60 years of age with osteopenia or osteoporosis and posterior pelvic ring fracture (sacrum) that is not grossly displaced are randomly divided into an operative and a conservative group after a low-energy trauma and the therapy success is compared. In total, the patients are followed for two years. The results are objectified by scientific questionnaires after 6 weeks, 6, 12 and 24 months regarding quality of life, pain, need for care and the ability to walk. The aim of the study is to determine the superiority of a therapeutic regime in terms of better quality of life, faster pain relief and/or less need for care.

Brief Summary in Scientific Language

Prospective randomized evaluation of the therapy (surgical versus conservative) of os sacrum insufficiency fractures in elderly patients (>60 or known osteoporosis/osteopenia). 65 patients per arm are planned, randomized 1-3 days after admission, the conservative group receives an opiod-supported analgesia and is immediately mobilized with pain-adapted full load. The operative arm receives a treatment of the fracture by transiliosacral screw osteosynthesis and external fixator from ventral or plate osteosynthesis of the pubic rami, also here a pain-adapted full load is allowed. Follow up: 2 years.

Organizational Data

- DRKS-ID: **DRKS00013703**
- Date of Registration in DRKS: **2018/12/10**
- 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**
-

DRKS-ID: **DRKS00013703**
Date of Registration in DRKS: **2018/12/10**
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.: **PV5550 , Ethik-Kommission der Ärztekammer Hamburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **S32.1 - Fracture of sacrum**
- ICD10: **S32.89 - [generalization S32.8: Fracture of other and unspecified parts of lumbar spine and pelvis]**

Interventions/Observational Groups

- Arm 1: **Operative therapy within 1-3 days - Transiliosacral screw fixation with one or two cannulated 7.3mm screw(s) through the os ilium and the vertebral bodies of S1 and possibly of S2.**
  Simultaneous application of an external anterior pelvis fixateur externe for 6 weeks or an ORIF (open reduction and internal fixation) with an angle-stable plate of the pubic ossis.

  Applies only to the operative arm:
  Change from conservative to operative, if adequate mobilisation cannot be achieved after 5 days due to pain, the patient is transferred from conservative to surgical group.
- Arm 2: **Conservative therapy: analgesia with opioids (oxycodone 10mg 2x daily) and an NSAID or paracetamol. Immediate mobilization under full load of the affected side with the help of physiotherapists.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***

Study Type: **Interventional**

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

Allocation: **Randomized controlled trial**

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

- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Mortality, pain intensity.

Scores of EQ5D, Tinetti-Gait and Barthel-Index after 6 weeks, after 6, 12 and 24 months.

Secondary Outcome

Morbidity and Quality of life.

Scores of VAS, EQ5D, Tinetti-Gait and Barthel-Index after 6 weeks, after 6, 12 and 24 months.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Universitätsklinikum Hamburg-Eppendorf, Hamburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/01/18**
- Target Sample Size: **130**
- Monocenter/Multicenter trial: **Monocenter trial**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2018/01/18**

Target Sample Size: **130**

Monocenter/Multicenter trial: **Monocenter trial**

- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **60 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

All patients who have a B2.1 posterior pelvic ring fracture after low-energy trauma AND are 60 years and older OR younger than 60 years and also suffering from osteporosis/osteopenia.

Exclusion criteria

Younger than 60 and no osteoporosis.
Unclear whether fresh or old injury.
Accident longer than 2 weeks ago.
High energy Trauma.

Addresses

- **Primary Sponsor**

UKE Hamburg EppendorfUnfall-, Hand- und Wiederherstellungschirurgie
Mr. Dr. med. Darius Thiesen
Martinistr. 52
20246 Hamburg
Germany

Telephone: **+4940741018014**
Fax: **[---]***
E-mail: **d.thiesen at uke.de**
URL: **[---]***

- **Contact for Scientific Queries**

UKE Hamburg EppendorfUnfall-, Hand- und Wiederherstellungschirurgie
Mr. Dr. med. Darius Thiesen
Martinistr. 52

Contact for Scientific Queries

UKE Hamburg EppendorfUnfall-, Hand- und Wiederherstellungschirurgie
Mr. Dr. med. Darius Thiesen
Martinistr. 52
20246 Hamburg
Germany

Telephone: **+4940741018014**
Fax: **[---]***
E-mail: **d.thiesen at uke.de**
URL: **[---]***

- **Contact for Public Queries**

UKE Hamburg EppendorfUnfall-, Hand- und Wiederherstellungschirurgie
Mr. Dr. med. Darius Thiesen
Martinistr. 52
20246 Hamburg
Germany

Telephone: **+4940741018014**
Fax: **[---]***
E-mail: **d.thiesen at uke.de**
URL: **[---]***

Sources of Monetary or Material Support

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

ZOM, Unfall-, Hand- und Rekonstruktive Chirurgie
UKE Uniklinikum Hamburg Eppendorf
Martinistraße 52
20246 Hamburg
Germany

Telephone: **040 74100**
Fax: **040 74100**
E-mail: **d.thiesen at uke.de**
URL: **www.uke.de**

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.*