Trial Description

Title

A prospective randomized moncenter trial comparing the clinical, functional and psychosocial outcome after treatment of syndesmosis ruptures with a static syndesmotic screw fixation or TightRope.

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

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Brief Summary in Scientific Language

The accuracy of syndesmosis reduction is essential when treating acute ankle fracture accompanied by syndesomis ruptures. Malreduction leads to an earlier osteoarthrosis in the ankle.
The aim of this study was to compare the long term clinical outcome of patients with syndesmosis ruptures, who were treated with static screw fixation or dynamic TightRope fixation.

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

No

Description IPD sharing plan

There will be a publication.

Organizational Data

- DRKS-ID: **DRKS00013562**
- Date of Registration in DRKS: **2017/12/07**
- 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.: **S-454/2017 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **S82.4 - Fracture of fibula alone**
- ICD10: **S82.8 - Fractures of other parts of lower leg**

Interventions/Observational Groups

- Arm 1: **Patients with syndesmosis rupture and implantation of static syndesmotic screw fiaxtion**
- Arm 2: **Patients with syndesmosis rupture and implantation of "Tight Rope"**

Characteristics

- 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

postoperative outcome measurement with several questionnaires and x-rays after 6 weeks, 3, 6 and 12 months:

"Fragebogen zum Vergleich Stellschraube vs TightRope"
"SF-12"
"Score of Olerud and Molander"
"VAS visual pain scale"
"Foot and ankle outcome score"

Outcome measurement with MRI only 3 months postoperatively

postoperative outcome measurement with several questionnaires and x-rays after 6 weeks, 3, 6 and 12 months:

"Fragebogen zum Vergleich Stellschraube vs TightRope"
"SF-12"
"Score of Olerud and Molander"
"VAS visual pain scale"
"Foot and ankle outcome score"

Outcome measurement with MRI only 3 months postoperatively

Secondary Outcome

postoperative measurement and comparison of the long term outcome in x-ray 6 weeks, 3, 6 and 12 months after implantation of screws or TightRope additionally with an MRI 3 months postoperatively and as appropriate with gait analysis

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Universitätsklinikum, Unfallchirurgisches Department, Heidelberg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/12/07**
- Target Sample Size: **50**
- 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

Patients of full age with a syndesmosis rupture

Exclusion criteria

younger than 18, approval disability, congenital deformity, missing approval, contraindication for MRI

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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Collaborator, Other Address

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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 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.*