



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

## Trial Description

### Title

**Evaluation of the influence of active controlled motion (ACM) after operatively treated ankle fractures type Weber-B and -C with the necessity for partial weightbearing for 6 weeks**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

[---]\*

### Brief Summary in Scientific Language

**Up to now there is almost no information about proprioceptive deficits after ankle fractures and their role in the rehabilitation process. However, it is known that in the knee joint there is no correlation between mechanical and subjective instability after rupture of the anterior cruciate ligament (ACL) but between proprioception and subjective instability and active controlled motion can decrease the proprioceptive deficit. Proprioceptive training of ankle fractures is commonly done with balance boards or balance circles. In patients with need of partial weightbearing this is not possible until full weightbearing is allowed. The aim of this study was to look for possible beneficial rehabilitation effects in the use of active controlled motion after operatively treated unstable ankle fractures with the need of partial weightbearing in the first six postoperative weeks.**

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

[---]\*

### Description IPD sharing plan

[---]\*

## Organizational Data

■ DRKS-ID: **DRKS00009979**



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- Date of Registration in DRKS: **2016/02/02**
- 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.: **159/10** , **Ethik-Kommission der Medizinischen Fakultät der Universität Würzburg**

## Secondary IDs

- Universal Trial Number (UTN): **U1111-1179-0173**

## Health condition or Problem studied

- ICD10: **S82.6 - Fracture of lateral malleolus**
- ICD10: **S82.8 - Fractures of other parts of lower leg**

## Interventions/Observational Groups

- Arm 1: **physiotherapy 2-3 times/weeks for 6 weeks postoperatively**
- Arm 2: **physiotherapy 2-3 times/weeks plus additional exercise 20 minutes a day with an active controlled motion device for 6 weeks postoperatively**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Randomized controlled trial**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Active control (effective treatment of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **I**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Range of motion of the ankle joint after 6 weeks**

### Secondary Outcome

**Range of motion of the ankle joint after 12 weeks; Range of motion of the subtalar joint after 6 and 12 weeks; changes in gait patterns after 6 and 12 weeks, results in questionnaires VAS FA, AOFAS, Mazur Score, Phillip-Score; Return to work**

### Countries of recruitment

- **DE Germany**

### Locations of Recruitment

- University Medical Center **Unfallchirurgie, Würzburg**

### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2010/11/01**
- 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: **99 Years**

### Additional Inclusion Criteria

**Operatively treated unstable ankle fractures type B- or C in the Weber classification between 01.11.2010-30.09.2011 with the need of partial weightbearing for six weeks as the only injury, age over 18 years, possibility to perform active controlled motion and no problems in walking before the injury; verbal and written consent to participate in the study**

### Exclusion criteria

**psychiatric comorbidities; unable to perform partial weightbearing**



**psychiatric comorbidities; unable to perform partial weightbearing**

## Addresses

### ■ Primary Sponsor

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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)**

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**Deutsches Register  
Klinischer Studien**

German Clinical  
Trials Register

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E-mail: [---]\*

URL: **www.klinik.uni-wuerzburg.de**

## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/01/10**

## 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.