Trial Description

Title

Activity tracking in elderly patients after operative treatment of proximal femur fractures

Trial Acronym

ACTProFem

URL of the trial

https://open.rsyd.dk/OpenProjects/da/openProject.jsp?openNo=238

Brief Summary in Lay Language

Elderly patients commonly suffer from hip fractures. These injuries are frequently associated with patients' dead, but objective tools to observe the recovery process are lacking. Physical activity is recognized as the key for the recovery process. Therefore, we think that activity trackers can reliably monitor the early phase after an operation and be used as this missing instrument. Standardized step counts are recorded using wearables or activity trackers and analyzed together with factors characterizing patient’s general and current health, epidemiology, and blood values. These data are the basis for the development of a 'traffic light' system. This can signal personal treatment demands and progress of recovery bz green/yellow/red colors. Data obtained by the used trackers enable a subgroup analysis of patients with femoral neck fractures, comparing two different standardized treatment methods in two different centers (Denmark and Germany). The regular use of wearables can be part of an individualized treatment in future and add a safety feature.

Brief Summary in Scientific Language

Elderly patients commonly suffer from proximal femoral fractures. These injuries are associated with a high mortality, however, objective tools to observe the recovery process are lacking. Physical activity is recognized as the key for the recuperation process. Therefore, we hypothesize that activity trackers can reliably monitor the early postoperative follow-up and be utilized as this missing instrument. Standardized step counts are recorded using wearables and analyzed in association with factors characterizing patient’s general and current health, epidemiology, and biochemical parameters. Minute-by-minute data are the basis for the development of a management-suited reporting system. This can facilitate signaling of personal treatment demands and progress of recovery. Data obtained by the used trackers enable a subgroup analysis of patients with femoral neck fractures, comparing two different standardized treatment methods in two different centers. The regular use of wearables can be part of an individualized treatment coordination in future and add a safety feature.

Organizational Data

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DRKS-ID: **DRKS00011934**

- Date of Registration in DRKS: **2017/04/10**
- 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.: **287/15 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1194-6780**
- Other Secondary-ID: **OP 238 (Odense patient data explorative network (OPEN))**

Health condition or Problem studied

- ICD10: **S72.0 - Fracture of neck of femur**
- ICD10: **S72.1 - Pertrochanteric fracture**
- ICD10: **S72.2 - Subtrochanteric fracture**

Interventions/Observational Groups

- Arm 1: **Activity measurement in patients suffering from a proximal femoral fracture including the locations AO 31 and 32**
- Arm 2: **Activity measurement in patients suffering from a forearm fracture including the locations AO 11, 12, 13, 21, 22 and 23 (upper extremity)**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Prognosis**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Percentage of the active time measured using an activity tracker and a threshold, which was adapted to this special patient population. The activity is registered at two time points: day 2+/-1 and 8+/-3 after surgery.

Secondary Outcome

Active minutes per day measured at two time points: day 2+/-1 and 8+/-3 after surgery, the questionnaire EQ-5D 3L (quality of life), the handicap index Barthel 20 based on questioning the patient and the nursing staff, complications are registered

Countries of recruitment

- DE **Germany**
- DK **Denmark**

Locations of Recruitment

- University Medical Center **Department of Orthopaedics and Traumatology, Freiburg im Breisgau**
- University Medical Center **Department of Orthopaedics and Traumatology, Odense**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/03/11**
- Target Sample Size: **126**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **65 Years**
- Maximum Age: **120 Years**

Additional Inclusion Criteria

•Existence of a proximal femoral fracture including the locations AO 31 and 32 (intervention group, n=48 per center)
•Or existence of a fracture of the upper extremity including the locations AO 11,12,13, 21, 22 and 23 (control group, n=15)

- **Age ≥ 65 years**
- **Being able to read and understand German or Danish**
- **Informed consent**

Exclusion criteria

- **Open fractures**
- **Polytrauma**
- **Colonization with multiresistent bacteria**
- **Preoperatively bedridden patients**
- **Infection of the wound**
- **Operative revisions because of other reasons**

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

■ **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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■ **Private sponsorship (foundations, study societies, etc.)**

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Private sponsorship (foundations, study societies, etc.)

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethical vote**
- trial protocol (mandatory for transfer to Studybox) **Protocol Version 2-0**

** 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.*