Trial Description

Title

Multicenter randomized controlled trial exploring postoperative complications and mobilization following major abdominal surgery with vs. without fitness tracker-based feedback (EXPELLIARMUS) - a CHIR-Net Student-Initiated German Medical Audit trial (CHIR-Net SIGMA trial)

Trial Acronym

EXPELLIARMUS

URL of the trial

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Brief Summary in Lay Language

In addition to survival, postoperative morbidity, i.e. the occurrence of complications, is the most patient-relevant aspect after major surgery. Some studies suggest that postoperative mobilization may reduce the incidence of complications, but the direct effect of enhanced mobilization of postoperative complications is unclear.
The main objective of the study is to investigate whether daily step goals in combination with a fitness wristband that provides feedback on the steps taken will result in fewer complications for patients undergoing major abdominal surgery than patients without this support (i.e. no step goals and no feedback via a fitness wristband).

Brief Summary in Scientific Language

Although mortality after major abdominal surgery has decreased significantly over the last decades, particularly in specialized centers, morbidity remains high. Reported complication rates in the literature vary in different study types. In major abdominal surgery, including laparoscopic surgery, complication rates between 30-60% have repeatedly been reported in RCTs. Interestingly, non-surgical complications like pulmonary and cardiac complications, deep vein thrombosis, urinary tract infections etc. constitute a substantial part of overall morbidity and could potentially be reduced by postoperative interventions. Early and enhanced postoperative mobilization has been advocated to reduce postoperative complications, but it is still unknown whether it can independently improve outcomes after major abdominal surgery and if so, how this is best implemented in daily clinical practice. Fitness trackers are a promising tool to improve postoperative mobilization following major abdominal surgery, but their effect on postoperative complications and recovery has not been studied in high-quality clinical trials.
The objective of this study is therefore to determine whether daily postoperative step goals and feedback via a fitness tracker and the health-care team about these step goals reduces the rate of postoperative complications following elective major abdominal surgery.

Organizational Data

- DRKS-ID: **DRKS00016755**
- Date of Registration in DRKS: **2019/03/06**
- 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-099/2019 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1228-3320**

Health condition or Problem studied

- Free text: **Patients undergoing major abdominal surgery**

Interventions/Observational Groups

- Arm 1: **Patients are fitted with a wearable fitness tracker on their wrist for the duration of their postoperative stay until discharge or a maximum of 30 days. Patients receive real-time visual feedback via the display of their tracker regarding daily steps taken and are encouraged to meet predefined daily step goals. In addition, ambulation is encouraged by the interprofessional care teams to meet these predefined step goals.**
- Arm 2: **Patients are fitted with a wearable fitness tracker on their wrist for the duration of their postoperative stay until discharge or a maximum of 30 days. The display of the device is disabled (blackened) and accordingly no feedback via the device is given. Patients are allowed to mobilize at will, i.e. as tolerated. Ambulation is encouraged by the interprofessional care teams according to local standard, but no specific mobilization protocol is provided.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Control group receives no treatment**
- Purpose: **Prevention**

Study Type: **Interventional**

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

Allocation: **Randomized controlled trial**

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

Who is blinded: **[---]***

Control: **Control group receives no treatment**

Purpose: **Prevention**

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

Primary Outcome

Postoperative complications measured via the comprehensive complication index (CCI) within 30 days after the index operation.

Secondary Outcome

1. Number of steps until POD 8 or until discharge.
2. QoR-15 at baseline and on POD 4 (or at discharge)
3. Activity data until discharge or a maximum of 30 days.
4. Health-related quality of life measured via the EORTC QLQ-C30 at baseline, on POD 8 (or discharge, whatever comes first) and on postoperative day 30
5. 6-minute walking test at POD 6 (or discharge, whatever comes first)
6. Time until return of bowel function measured via the GI-2 score
7. Postoperative pulmonary complications according to the Melbourne group score during hospital stay
8. Deep vein thrombosis until POD 30
9. Pulmonary embolism until POD 30
10. Time from day of index surgery to achieve uninterrupted ambulation greater than 10 min.
11. 30-day mortality
12. Length of hospital stay
13. Discharge destination from the acute hospital ward
14. Pain via the numeric rating scale on POD 2,4,6 at rest and during movement
15. Postoperative unintended falls/collapses until day of discharge

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Allgemein-, Viszeral- und Transplantationschirurgie, Heidelberg**
- University Medical Center **Chirurgische Klinik Universitätsmedizin Mannheim, Mannheim**
- University Medical Center **Charité – Universitätsmedizin Berlin, Berlin**
- University Medical Center **Klinik der Allgemein- und Viszeralchirurgie , Frankfurt a.M.**
- University Medical Center **Klinik für Allgemein-, Viszeral- und Kinderchirurgie, Göttingen**
- University Medical Center **Klinik für Allgemein-, Viszeral- und Thoraxchirurgie, Hamburg-Eppendorf**
- University Medical Center **Kiel**
- University Medical Center **Klinikum der Universität München · Klinik für Allgemein-, Viszeral-, Transplantations- und Gefäßchirurgie , München**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/06/04**
- Target Sample Size: **348**
- 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

Preoperative inclusion criteria:
1. Patients scheduled for elective major abdominal surgery defined as procedures expected to last more than 2 hours, or with an anticipated blood loss greater than 500 ml
2. Ability to understand the character and individual consequences of the clinical trial
3. Open or laparoscopic or robotic surgery or any variant (laparoscopic-assisted, hybrid procedures etc.)
4. Written informed consent
5. Age ≥18 years

Intra-/postoperative inclusion criteria:
1. Expected postoperative stay on the intensive care or intermediate care ward is less than 4 days.
2. No planned reoperation within 30 days
3. Confirmed major abdominal surgery (=defined as procedures expected to last more than 2 hours, or with an anticipated blood loss greater than 500 ml.

Exclusion criteria

1. American Society of Anesthesiologists (ASA) grade >3
2. Preoperative immobility or inability to walk unaided
3. Participation in another interventional trial with interference of intervention and outcome of this study
4. Expected postoperative stay on the intensive care or intermediate care ward >= 4 days
5. Planned reoperation within 30 days after index operation
6. Planned abdominal-thoracic operations (two-field surgeries)

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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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.*