## Trial Description

### Title

Protocol based Mobilization on Intensive Care Units

### Trial Acronym

PRO-MOTION

### URL of the trial

[---]*

### Brief Summary in Lay Language

Protocols for mobilization shall be implemented on 5 Intensive Care Units. Protocols include daily assessment for mobility, in- and exclusion criteria, assessment, checklist, safety criteria and ICU mobility scale. Implementation will be in randomized order. Each month before and after implementation, mobilization of patients will be assessed. Duration of the study will be 7 months. Aim of the study is to test, whether the implementation of a protocol leads to a higher rate of mobilizations, and other parameters as length of mechanically ventilation, delirium or stay on Intensive Care Unit and hospital will be affected.

### Brief Summary in Scientific Language

Multicenter, stepped-wedge cluster-randomized pilot study for mobilization of patients on Intensive Care Units

## Organizational Data

- **DRKS-ID:** DRKS00012399
- **Date of Registration in DRKS:** 2017/05/08
- **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.:** D 447/17, Ethikkommission der Christian-Albrechts-Universität zu Kiel

## Secondary IDs

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Health condition or Problem studied

- Free text: Early Mobilization of critically ill patients

Interventions/Observational Groups

- Arm 1: Stepped-wedge Design. Intervention is implementation of a protocol for early mobilization. Patients of the interventional group are patients after the implementation of a protocol
- Arm 2: Control group are patients before implementation

Characteristics

- Study Type: Interventional
- Study Type Non-Interventional: [---]*
- Allocation: Randomized controlled trial
- Blinding: [---]*
- Who is blinded: [---]*
- Control: Control group receives no treatment
- Purpose: Supportive care
- Assignment: Parallel
- Phase: N/A
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): N/A

Primary Outcome

Percentage of patients during 7 one-day point prevalence surveys before and after implementation of a protocol, who are mobilized on the edge of bed or higher, assessed by ICU Mobility Scale >=3.

Secondary Outcome

Presence and/or length of mechanically ventilation, delirium, stay on ICU and in hospital, barriers to early mobilization, unwanted safety events, and process parameters as identified barriers, used strategies and adaptions to local conditions

Countries of recruitment

- DE Germany
Locations of Recruitment

- University Medical Center Klinik für Anästhesiologie und Intensivmedizin, Kiel
- Medical Center Städtisches Krankenhaus, Kiel
- University Medical Center Klinikum Oldenburg, Oldenburg
- Medical Center Klinikum Neumarkt, Neumarkt
- University Medical Center Klinik für Innere Medizin, Kiel

Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2017/07/28
- Target Sample Size: 360
- 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

- min 18 years old
- physician's order for early mobilization

Exclusion criteria

- high risk of dying within the next days, due to the estimation of study personal (palliative state)
- no consent in research with patient’s data
- participated already in a previous prevalence survey
- take part in a concurrent study with endpoints such as mobilization, length of stay, length of mechanically ventilation, presence or length of delirium

Addresses

- Primary Sponsor
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  Mr. Peter Nydahl
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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 complete, follow-up complete**
- Study Closing (LPLV): **2018/02/28**

**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.