Trial Description

Title

Perioperatively-Acquired Weakness

Trial Acronym

POAW

URL of the trial

[---]*

Brief Summary in Lay Language

It is a well-known concomitant that intensive care patients suffer from acquired muscle weakness that can negatively affect the acute course of the disease and long-term recovery. This muscle breakdown is initiated by immobilization and inflammatory reactions. There is clear evidence that this muscle breakdown begins within a few hours and may even occur during surgery. The acquired muscle damage can then have a significant impact on the recovery process of patients, even if they do not require intensive care treatment. An association with postoperative complications such as hospital acquired pneumonia and immobility seems plausible.
The aim of the study is to investigate if and which patients already suffer from muscle weakness after surgery or after anesthesia for an examination. Both the muscle mass and function of the extremities, as well as the respiratory muscles are examined. Furthermore, the aim of the study is to identify risk factors that lead to the development of muscle weakness. In addition, external influencing factors such as duration and kind of surgery, as well as laboratory investigations, which map the inflammatory process in the body as well as the metabolic pathways for the regulation of the skeletal muscle mass are examined.

Brief Summary in Scientific Language

Muscle weakness acquired in the intensive care unit is associated with poor outcome in terms of muscle strength and function as well as reduced health-related quality of life. Muscle loss is favored by immobilization and inflammation and is ubiquitous in the intensive care unit. There is clear evidence that this muscle breakdown can occur within a few hours or even perioperatively. Perioperative muscle loss can then have a significant impact on the recovery process of patients, even if they do not require intensive care treatment. An association with postoperative complications such as pneumonia and immobility seems plausible.
The aim of the study is to investigate whether and which patients already develop muscle weakness through the perioperative course. Both the muscle mass and function of the extremities, as well as the respiratory muscles are examined. Furthermore, the aim of the study is to identify risk factors that lead to the development of significant muscle weakness. To describe the risk factors we also includes the determination of the inflammatory immune response of the patient from the blood. Interleukins and cortisol have a significant effect on muscle metabolism and were induced intraoperatively. Whether a direct connection exists

here has be investigated.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00015637**
- Date of Registration in DRKS: **2018/12/10**
- 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.: **EA2/221/17 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **M62.5 - Muscle wasting and atrophy, not elsewhere classified**

Interventions/Observational Groups

- Arm 1: **Patients with elective surgery without tumor disease without significant comorbidities.**
- Arm 2: **Patients undergoing anesthesia without surgery (e.g., MRI or CT diagnosis under general anesthesia) to differentiate the operative stressor from the influence of anesthesia itself**
- Arm 3: **Patients with elective tumor surgery often associated with tumor sarcopenia, which may affect muscle weakness**

Characteristics

- Study Type: **Non-interventional**
-

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Study Type Non-Interventional: **Other**

- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Diagnostic**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Loss of muscle strength on the first postoperative day measured by hand grip strength (hand grip strength measured by dynamometry on both sides)

Secondary Outcome

- Questionnaire on Physical Independence (Functional Independence Measure)
- Clinical muscle strenght measurement (MRC score)
- lung function tests
- Ultrasound examination of the musculature
- 6-minute walking test
- indirect calorimetry

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Charité Universitätsmedizin Berlin, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/11/27**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Monocenter trial**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2018/11/27**

Target Sample Size: **100**

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 undergoing elective surgery at the Charité
- Patients undergoing elective diagnostics in General anaesthesia at the Charité
- written consent of the patient

Exclusion criteria

- Age <18 years
- Participation in another study
- neuromuscular disease
- lack of consent of the patient
- pregnancy

Addresses

- **Primary Sponsor**

Charité Campus Virchow-Klinikum
Augustenburger Platz 1
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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.*