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

Trial Description

Title

Indication and outcome of decompressive laparotomy for abdominal compartment syndrome under extracorporeal membrane oxygenation

Trial Acronym

ECMO DL

URL of the trial

[---]*

Brief Summary in Lay Language

In the last decades, extracorporeal membrane oxygenation is increasingly used on intensive care units. Indications are respiratory failure, support of cardiogenic shock and extracorporeal cardiopulmonary resuscitation. A potential complication of critical care patients is the adbominal compartment syndrome, in which the abdominal pressure increases, inhibiting mechanical ventilation and possibly leading to cardiac arrest. The treatment for abdominal compartment syndrome is opening the adbomen (so called decompressive laparotomy) to lower the intraadbominal pressure. Abdominal compartment syndrome is a frequent complication under extracorporeal membrane oxygenation. Risk factors and outcome are not observed to date on adult patients.

Brief Summary in Scientific Language

Utilisation of ECMO has increased in the last decades. Abdominal compartment syndrome can complicate the clinical course of ECMO patients. Regularly, a bedside decompressive laparotomy (DL) is undertaken. Mortality for ECMO itself, as for DL is high. Risk factors for the development of abdominal compartment syndrome under ECMO therapy and the outcome of DL under ECMo is not examined to date on an adult cohort. For our analysis we observe all ECMO patients during a 2,5 year intervall concerning indications, risk factors and outcome.

Organizational Data

- DRKS-ID: **DRKS00013672**
- Date of Registration in DRKS: **2018/01/10**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **No approval required according to**

DRKS-ID: **DRKS00013672**
Date of Registration in DRKS: **2018/01/10**
Date of Registration in Partner Registry or other Primary Registry: **[---]***

Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

EC

- (leading) Ethics Committee Nr.: **267/17 , Ethik-Kommission der Medizinischen Fakultät der Rheinischen Friedrich-Wilhelms-Universität Bonn**

Secondary IDs

Health condition or Problem studied

- ICD10: **R19.8 - Other specified symptoms and signs involving the digestive system and abdomen**
- ICD10: **J80.0 - [generalization J80: Adult respiratory distress syndrome]**
- ICD10: **I21.9 - Acute myocardial infarction, unspecified**
- ICD10: **I25.1 - Atherosclerotic heart disease**
- ICD10: **I08.9 - Multiple valve disease, unspecified**
- ICD10: **I27.9 - Pulmonary heart disease, unspecified**
- ICD10: **I26 - Pulmonary embolism**

Interventions/Observational Groups

- Arm 1: **Retrospective analysis of our anonymized ECMO--database. ECMO without DL. Observed parameters: age, gender, body mass index, total hospital stay, hospital stay post-ECMO, hospital stay post-DL, Intensive care unit (ICU) stay, ICU stay post-ECMO, ICU-stay post-DL, ECMO start, duration of ECMO therapy, use of a left-ventricular assist device, CPR pre-ECMO, ECMO-mode (veno-venous/veno-arterial), time of DL, duration of ECMo until DL, diagnosis for ECMO, blood gas analysis of DL-patients pre and post DL, flow on ECMO pre and post DL, fluid balance 24 h before DL, Simplified Acute Physiology Score (SAPS) II on ICU admission and ECMO-start, Therapeutic Intervention Scoring System (TISS) on ICU-admission and ECMO-start, Charlson Comorbidity Index**
- Arm 2: **Retrospective analysis of our anonymized ECMO--database. ECMO with DL. Observed parameters: age, gender, body mass index, total hospital stay, hospital stay post-ECMO, hospital stay post-DL, Intensive care unit (ICU) stay, ICU stay post-ECMO, ICU-stay post-DL, ECMO start, duration of ECMO therapy, use of a left-ventricular assist device, CPR pre-ECMO, ECMO-mode (veno-venous/veno-arterial), time of DL, duration of ECMo until DL, diagnosis for ECMO, blood gas analysis of DL-patients pre and post DL, flow on ECMO pre**

and post DL, fluid balance 24 h before DL, Simplified Acute Physiology Score (SAPS) II on ICU admission and ECMO-start, Therapeutic Intervention Scoring System (TISS) on ICU-admission and ECMO-start, Charlson Comorbidity Index

Characteristics

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

Primary Outcome

Mortality of ACS treated with DL under ECMO

Secondary Outcome

Hospital stay, ICU stay, risk factors (mortality, DL)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik und Poliklinik für Allgemein-, Viszeral-, Thorax- und Gefäßchirurgie und Klinik und Poliklinik für Anästhesiologie und Operative Intensivmedizin, Bonn**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/09/01**
- Target Sample Size: **175**
- Monocenter/Multicenter trial: **Monocenter trial**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2017/09/01**

Target Sample Size: **175**

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

ECMO-therapy on adult patients independent of underlying diagnosis between 03/2014 and 09/2016

Exclusion criteria

Age under 18 years

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 complete, follow-up complete**
- Study Closing (LPLV): **2017/10/01**

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum**
- trial protocol (mandatory for transfer to Studybox) **Prüfprotokoll**

** 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.*