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

Trial Description

Title

Data analysis of patients with Extracorporeal memebranoxygenation/ extracorporeal Life Support within the HELP-Project

Trial Acronym

HELP-Study

URL of the trial

[---]*

Brief Summary in Lay Language

The study includes special treatment for emergency patients. This so called ECMO/ECLS treatment is used to support or replace the normal heart or lung function, to give time for solving organ based problems.
With this study patients, treated with ECMO/ECLS, due to severe organ failure, were examined to assess the outcomes and long-term quality-of life of patients supported by extracorporeal membrane oxygenation (ECMO) and extracorporeal life support (ECLS) treated in our Hallesches Extracorporeal Life-support Program (HELP).

Brief Summary in Scientific Language

Despite all medical advances and implementations of the current guidelines cardiopulmonary organ failure remains a leading cause of death in intensive care, regardless of etiology. The mortality remains high with up to 70%.
The extracorporeal membrane oxygenation (ECMO) and extracorporeal life support (ECLS) - System are intensive care techniques, through the use of which organ functions of the heart or the lungs are partially or fully adopted. This treatment is used in patients who are faced with severe organ damage or dysfunctions in particular to the heart and lungs as cardiogenic shock or ARDS. It is accepted and supports the function of the affected organ over the necessary period.
These systems can ensure adequate oxygenation and perfusion over days or weeks. That is why they are used in cardiac (e.g. heart failure, myocardial infarction or pulmonary embolism with cardiogenic shock) and pulmonary diseases (eg, ARDS).
Cardiac disease forms are treated with a veno-arterial access to support or replace cardiac function through the centrifugal pump of the system. In pulmonary organ failure a veno-venous connection is made to perform an extracorporeal oxygenation of the blood through the oxygenator and so relieve the lungs.
Due to still existing high risks and complication rates and the necessary experience in dealing with ECLS / ECMO patients it is recommended that the treatment is carried out in specialized centers.
Through the establishment of a hospital-wide ECMO / ECLS experienced

emergency teams that spot within the same hospital the ECMO / makes ECLS implantation and performs the consecutive patients transportation to a specialized center, could the poor survival rate of patients with cardiac arrest outside of a ECMO / ECLS Centre of 4-13% be raised to 55%. Organized by competence centers - - Especially against the background of a better outcome of patients with acute heart or pulmonary failure, an establishment of mobile ECMO / ECLS team seems promising. Therefore, the inter-regional "Hallesche Extracorporeal Life Support Program" (HELP) at the University Hospital Halle (Saale) was launched in 2010 Under this project the mobile HELP team can be contacted in case of acute cardiac / respiratory failure via a 24-hour emergency hotline by external clinics and are transported on the indication for an ECMO / ECLS system within a very short time there. The patient is supplied with a portable extracorporeal device on site and surface or airborne tied to the University Hospital Halle laid the HELP team.
The aim of the retrospective observational study is to investigate the charges preinterventional, hospital and follow-up data of the previously under the HELP patients treated systematically as there are insufficient data on the patient population described in the literature.

References:
- Combes et al. - Outcomes and Long-Term Quality-of-life of patients supported by extracorporeal membrane oxygenation for refractory cardiogenic shock; Crit Care Med 2008; 36 (5): 1404-11.

Organizational Data

- DRKS-ID: **DRKS00009735**
- Date of Registration in DRKS: **2016/03/03**
- 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.: **2015-112 , Ethikkommission der Medizinischen Fakultät der Martin-Luther-Universität Halle Wittenberg**

Secondary IDs

Health condition or Problem studied

- Other: **ICD-10-CM: Z92.81 extracorporeal membrane oxygenation (ECMO)**
- Other: **OPS: 8-852 Extrakorporale Membranoxygenation (ECMO) und Prä-ECMO-Therapie**

Interventions/Observational Groups

- Arm 1: **There is a retrospective analysis of the HELP Patients who emergency supplied with a life-support device and were treated on different ICUs of University Hospital Halle (Saale) . This includes data Uplifting drying before and after ECMO / ECLS implantation, as well as the follow-up, including quality of life detection.**

Characteristics

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

Primary Outcome

Systematic data analysis of patients with extracorporeal membrane oxygenation Extra / extracorporeal life support in the framework of the HELP project. Analysis survival of the HELP ECMO / ECLS patients at hospital.

Secondary Outcome

none

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Herzchirurgie, Anästhesie, Halle Saale**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/09/15**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2015/09/15**

- Target Sample Size: **71**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **16 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

patients treated with ECMO or ECLS in HELP-project

Exclusion criteria

patient which were not treated with ECMO or ECLS in HELP-project

patients treated with ECMO or ECLS, but where not in the HELP-project

Addresses

- **Primary Sponsor**

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  Fax: **[---]***
  E-mail: **[---]***
  URL: **www.medizin.uni-halle.de**

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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): **2015/12/18**

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.*