Trial Description

Title

Subcutaneously administered low molecular weight heparin for anticoagulation in patients undergoing lung transplantation with periprocedural ECMO support - a retrospective, observational cohort study.

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Extracorporeal membrane oxygenation (ECMO) can be used as an organe replacement procedure before and after lung transplantation. During ECMO therapy anticoagulation (i.e. the use of blood thinners) is deemed necessary. Currently, unfractioned heparin (UFH) is the most commonly used anticoagulant in this setting. The aim of this retrospective, observational study is to compare the use of UFH with low molecular weight heparin (LMWH) for anticoagulation during ECMO.

Brief Summary in Scientific Language

In a selected patient population with end-stage lung disease lung transplantation represents the only potentially live saving therapy. In patients who experience severe deterioration while being scheduled for lung transplantation extracorporeal membrane oxygenation (ECMO) therapy can be used as bridge-to-transplant while waiting for a compatible organ. ECMO can also be used as bridge-to-recovery therapy in lung transplanted patients and may be initiated postoperatively in case of primary graft disfunction. Due to the patients' blood being exposed to a large artifical surface, anticoagulation is deemed necessary during ECMO therapy. Currently, there is no ideal, evidence based anticoagulation regimen available and despite its limitations, unfractioned heparin remains the most commonly used substance for anticoagulation during ECMO.
The aim of this retrospective cohort study is to compare the use of low molecular weight heparin (LMWH) versus unfractioned heparin (UFH) for anticoagulation during ECMO therapy. For this purpose, all patients that underwent lung transplantation and needed any form of periprocedural ECMO support at the Medical University of Vienna between 2006 and 2017 will be screened for inclusion- and exclusion criteria and grouped in two cohorts.
Subsequently, the occurrence of the primary outcome parameter "severe bleeding" as well as the secondary outcome parameter "thromboembolic event" will be compared between the two cohorts with different anticoagulation.

Organizational Data

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DRKS-ID: **DRKS00013593**

- Date of Registration in DRKS: **2017/12/12**
- 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.: **EK 1017/2017 , Ethikkommission Medizinische Universität Wien, Borschkegasse 8, 1090 Wien, Österreich, http://ethikkommission.meduniwien.ac.at**

Secondary IDs

Health condition or Problem studied

- Free text: **lung transplantation**
- Free text: **extracorporeal membrane oxygenation**
- ICD10: **Z94.2 - Lung transplant status**

Interventions/Observational Groups

- Arm 1: **Unfractioned heparin (UFH) for anticoagulation during ECMO therapy.**
- Arm 2: **Low molecular weight heparin (LMWH) for anticoagulation during ECMO therapy.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The history of included patients will be screende for severe bleeding events (surgical intervention for bleeding control, intracranial bleeding, uncontrollable bleeding).

Secondary Outcome

The history of included patients will be screened for thromboembolic events (arterial thromboembolic events, including myocardial infarction and stroke, venous thromboembolism including pulmonary embolism and extracorporeal thrombosis).

Countries of recruitment

- AT **Austria**

Locations of Recruitment

- University Medical Center **Medizinische Universität Wien, Wien**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/12/14**
- Target Sample Size: **125**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

- lung transplantation
- between 01/01/2006 and 04/30/2017
- perioperative ECMO support
- anticoagulation with UFH or LMWH
- acceptable data consistency

Exclusion criteria

none

none

Addresses

- **Primary Sponsor**

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  Währinger Gürtel 18-20
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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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- **Private sponsorship (foundations, study societies, etc.)**

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  Austria

  Telephone: **+4314064810**
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  URL: **www.oegari.at**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2018/03/31**

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.*