

# Therapy individualisation for patients with acute respiratory distress syndrome according to blood flow

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<b>Registration date</b> 15/08/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/08/2018	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Acute respiratory distress syndrome (ARDS) is a life-threatening lung condition that results in the lungs not being able to supply the rest of the body with enough oxygen. There are various approaches for treating ARDS, including being attached to a breathing machine or muscle relaxants; however, the mortality rate of ARDS is still high. Another approach for the treatment of ARDS is extracorporeal membrane oxygenation (ECMO), a process where blood is removed from the body so that carbon dioxide can be removed from red blood cells artificially, and then can be re-supplied with oxygen before going back into the body. However, there has been little research into whether ECMO improves the outcome of ARDS. Personalising ECMO treatment to the patient may help to improve its effectiveness, along with adapting it to the patient's blood flow.

This study aims to improve the survival and outcome of patients with ARDS using ECMO with blood flow monitoring.

### Who can participate?

Adults with ARDS

### What does the study involve?

Patients will be equipped with a device that provides ECMO, along with a blood flow monitoring system. Various measurements of cardiac output and the effects of ECMO will be taken using the monitoring system.

### What are the possible benefits and risks of participating in the study?

The possible benefit to participants taking part in this study is that they will receive a precise analysis of their cardiovascular and circulatory status. There are no additional risks to participants taking part in this study, as participants will already be equipped with the blood flow monitoring system as part of their standard treatment.

### Where is the study run from?

General Intensive Care Unit of Munich University Hospital (Germany)

When is the study starting and how long is it expected to run for?  
October 2011 to December 2017

Who is funding the study?  
Technical University of Munich (Germany)

Who is the main contact?  
direction.med2@mri.tum.de

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
310/185

## Study information

**Scientific Title**  
Transpulmonary thermodilution before and during veno-venous extra-corporeal membrane oxygenation: an observational study on a potential loss of indicator into the extra-corporeal circuit

**Study objectives**  
The aim of this observational study was to analyze the changes in transpulmonary thermodilution-derived (TPTD) parameters during initiation of extra-corporeal membrane oxygenation (ECMO) in patients with severe acute respiratory distress syndrome (ARDS) with regard to a potential loss of indicator in the extracorporeal circuit. It aims to address the following questions:

1. Does TPTD derived parameters increase after the onset of ECMO?
2. Does ECMO influence differently the TPTD derived CO (Stewart-Hamilton equation) and EVLW and GEDV (Newman approach of consecutive mix-chambers)?
3. Does the closer proximity of the indicator injection to the femoral ECMO-drainage cannula stronger impact on the loss of indicator?

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethikkommission; Fakultät für Medizin; Technische Universität München, 01/08/2018, 310/18S

## **Study design**

Observational single-centre cohort study

## **Primary study design**

Observational

## **Study type(s)**

Diagnostic

## **Health condition(s) or problem(s) studied**

Acute respiratory distress syndrome (ARDS)

## **Interventions**

Participants were indicated for hemodynamic monitoring (transpulmonary thermodilution (TPTD)) and extracorporeal membrane oxygenation (ECMO) with very severe acute respiratory distress syndrome (ARDS), independently from the study by the ICU physician in charge. Patients were equipped with the advanced hemodynamic monitoring system (PiCCO). Triplicate TPTD measurements were performed with 15 ml cold saline solution via a conventional central venous catheter (CVC) at least 3 times per day (as standard).

Patients fulfilling the criteria for very severe ARDS were equipped with the extracorporeal circuit (Novalung) for ECMO. 2 triplicate TPTDs were performed before connection to the extracorporeal circuit, followed by another 2 TPTDs after this. The observational time period from the first to the last TPTD measurement was approximately 16 hours. The first measurement will be 8 hours prior to ECMO initiation, the second will be immediately prior to the ECMO initiation, the third will be immediately after ECMO initiation, and the final will be 8 hours after ECMO initiation.

All patients received normal routine care and there was no follow-up period.

## **Intervention Type**

Device

## **Primary outcome(s)**

Differences in global end diastolic volume index (GEDVI), extravascular lung water index (EVLWI) and cardiac output (CO), assessed using transpulmonary thermodilution:

1. Between patients with jugular and femoral central venous catheter (CVC) before the initiation of extracorporeal membrane oxygenation (ECMO)
2. Before and during ECMO within groups of patients with jugular and femoral indicator injection

## **Key secondary outcome(s)**

The following are assessed using transpulmonary thermodilution (TPTD) and pulse contour analysis (PCA) 8 hours prior to initiation of ECMO, immediately prior to ECMO, immediately after initiation of ECMO and around 8 hours after ECMO:

1. Comparison of the final ECMO-flow for patients with jugular and femoral group.
2. Comparison of the next-to-last measurements before ECMO and the second TPTDs under the target ECMO-flow.

3. Comparison of the differences of TPTD-values before and during ECMO between the groups with jugular and femoral indicator injection.
4. Analyzing the change in TPTD-values induced by the extracorporeal circuit by multiple regression analysis.

**Completion date**

31/12/2017

## Eligibility

**Key inclusion criteria**

1. Aged 18 or older
2. Critically ill
3. Severe acute respiratory distress syndrome (ARDS)
4. Extracorporeal membrane oxygenation
5. Trans-pulmonary thermodilution monitoring

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Pregnant

**Date of first enrolment**

01/01/2012

**Date of final enrolment**

31/08/2017

## Locations

**Countries of recruitment**

Germany

**Study participating centre**

**II. Medizinische Klinik und Poliklinik, Klinikum rechts der Isar der Technischen Universität München**  
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81675

## Sponsor information

### Organisation

II. Medical Department, Klinikum rechts der Isar, Technische Universität München

### ROR

<https://ror.org/04jc43x05>

## Funder(s)

### Funder type

Not defined

### Funder Name

II. Medical Department, Klinikum rechts der Isar, Technische Universität München

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during the current study are available upon request from Alexander Herner ([alexander.herner@mri.tum.de](mailto:alexander.herner@mri.tum.de)) or Wolfgang Huber ([wolfgang.huber@mir.tum.de](mailto:wolfgang.huber@mir.tum.de)) The data will be available following permission from the Institutional Review Board.

### IPD sharing plan summary

Available on request