ISRCTN12607675 https://doi.org/10.1186/ISRCTN12607675

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

Submission date	Recruitment status	[ ] Prospectively registered
08/08/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/08/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/08/2018	Respiratory	[ ] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
310/18S

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 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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available.

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). Tripicate TDTP 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 measure
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

Secondary outcome measures
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.

Overall study start date
16/10/2011

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 oxgenation
5. Trans-pulmonary thermodilution monitoring

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
14

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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Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/04jc43x05

Funder(s)

Funder type
Not defined

Funder Name
II. Medical Department, Klinikum rechts der Isar, Technische Universtität München

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
01/09/2018

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) or Wolfgang Huber (wolfgang.huber@mir.tum.de) The data will be available following permission from the Institutional Review Board.

IPD sharing plan summary
Available on request