

Prediction of outcome in patients with lung impairment: a prospective comparison using different scores

Submission date 16/06/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/06/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/07/2023	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Despite several effective treatment approaches including prone positioning and low tidal volume, acute respiratory distress syndrome (ARDS, an acute lung impairment) still carries a high mortality. Therefore, extracorporeal lung membrane oxygenation (ECMO, a way of getting blood oxygenated outside the body) is also used. Despite more than 40 years of clinical use of ECMO, it remains controversial. This might be related to its use as a rescue treatment in the first clinical studies. Analysis of previous studies suggests that starting ECMO earlier might be beneficial. However, there is still controversy regarding which patients should be treated with ECMO according to which criteria, and also which interval after the start of mechanical ventilation (breathing support) provides the best effect size of ECMO compared with conventional treatment.

Most of the recent and ongoing studies include patients based on the recent ARDS definitions (Berlin; American European Consensus Conference AECC) and on scoring systems like the lung injury score (LIS). However, there is a lack of studies with systematic repeated comparison of the predictive capabilities of these scores over time. In addition to the traditional definitions and scores, other parameters such as the oxygenation index (OI, an index which is calculated using airway pressure, fraction of inspired oxygen and arterial partial pressure of oxygen) or the extravascular lung water index (EVLWI, an index which is used to quantify the amount of fluid outside the pulmonary vessels) might predict the outcome even better than the definitions and scoring systems used to date.

Therefore, the aim of this study is to compare the predictive capabilities of the oxygenation index, AECC and Berlin definitions of ARDS (definitions of ARDS that were suggested from expert consensus conferences), the Murray score and its total score without radiological points (Murray-WRP) as well as EVLWI, regarding 28-days mortality.

Who can participate?

Patients aged 18 or older with ARDS according to the Berlin definition

What does the study involve?

Daily measurement of AECC- and Berlin-definition of ARDS, modified Murray score without

radiological points (Murray_mod) and oxygenation index (OI) for four days after intubation. Documentation of haemodynamic (blood flow) parameters derived from transpulmonary thermodilution (TPTD, a way of measuring different parameters for lung and heart function) and pulse contour analysis (PCA, a way of measuring cardiac output; PiCCO; Pulsion Medical Systems; Feldkirchen, Germany), if PiCCO monitoring (a medical device used for haemodynamic observations) is available irrespective of the study.

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

The possible benefit is a very thorough analysis and monitoring of pulmonary and haemodynamic parameters. There are no additional risks to participants due to the observational design of the study.

Where is the study run from?

General Intensive Care Unit R3a (2/11) of the university hospital Klinikum rechts der Isar, Technical University of Munich (Germany)

When is the study starting and how long is it expected to run for?

May 2015 to September 2016

Who is funding the study?

Technical University of Munich (Germany)

Who is the main contact?

Prof. Wolfgang Huber

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Prediction of outcome in patients with ARDS: a prospective comparison of ARDS-definitions and other ARDS-associated parameters, ratios and scores at intubation and over time

Study objectives

The aim of this observational study was to compare the predictive capabilities of the oxygenation-index OI (mean airway pressure*FiO₂/pO₂), AECC- and Berlin-definitions of ARDS, single components of Murray-score and its total score without radiological points (Murray-WRP) as well as the EVLWI regarding ICU-, 28-days- and hospital mortality.

Main questions addressed by the study:

1. Which day among days 1-4 provides the best prediction of 28-day mortality?
2. Which score or parameter provides the best prediction of 28-day mortality in general?
3. In patients with PiCCO-monitoring available: Does measurement of extravascular lung water index (EVLWI) provide additional prognostic information?
4. Are there hints that advanced haemodynamic monitoring "per se" might improve the prognosis of patients with ARDS?
5. Are there hints that the inclusion criteria of the EXODUS trial should be modified?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/08/2018, Ethikkommission der Technischen Universität München (Prof. Dr. Georg Schmidt, Ismaninger Straße 22, 81675 München, Germany, Tel: +49 (0)89 4140 4371; Email: ethikkommission@mri.tum.de), ref: 343/18 S

Study design

Single-center observational cohort study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Acute respiratory distress syndrome (ARDS)

Interventions

Due to the observational design of the study no specific intervention related to the study was performed. Routine data of patients with ARDS and (if available irrespective of the study) data from PiCCO monitoring were documented for up to 10 days after intubation. All measurements were repeated at least once per day.

Daily measurement of AECC- and Berlin-definition of ARDS, modified Murray-score without radiological points (Murray_mod) and oxygenation index (OI) for four days after intubation. Documentation of haemodynamic parameters derived from transpulmonary thermodilution (TPTD) and pulse contour analysis (PCA; PiCCO; Pulsion Medical Systems; Feldkirchen, Germany), if the PiCCO-monitoring is available irrespective of the study.

All patients received normal routine care and there was no follow-up period beyond 28-day mortality.

Intervention Type

Other

Primary outcome(s)

28-day mortality measured using medical records

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

30/09/2016

Eligibility

Key inclusion criteria

1. Aged 18 or older
2. Critically ill
3. Acute respiratory distress syndrome (ARDS) according to Berlin Definition

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

100

Key exclusion criteria

Pregnancy

Date of first enrolment

28/05/2015

Date of final enrolment

06/09/2016

Locations**Countries of recruitment**

Germany

Study participating centre

Technische Universität München

Medizinische Klinik und Poliklinik II

Klinikum rechts der Isar

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Sponsor information**Organisation**

Technische Universität München

ROR

<https://ror.org/02kkvpp62>

Funder(s)**Funder type**

University/education

Funder Name

Technische Universität München

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during the current study are available upon request from Paul Schmidle (paul.schmidle@mri.tum.de) and 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/05/2020	19/07/2023	Yes	No