ISRCTN32938630 https://doi.org/10.1186/ISRCTN32938630

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

Submission date
16/06/2019

Recruitment status
No longer recruiting

Registration date
21/06/2019

Overall study status
Completed

Last Edited
19/07/2023

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

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 irrespectively 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 irrespectively 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 measure
28-day mortality measured using medical records

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/05/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

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
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Sponsor information

Organisation
Technische Universität München

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02kkvpp62

Funder(s)

Funder type
University/education

Funder Name
Technische Universität München

Results and Publications

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

Intention to publish date
01/08/2019

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