The effect of inspiratory oxygen fraction on the ratio of partial arterial oxygen pressure and inspiratory oxygen fraction (PaO2/FiO2 ratio) in mechanically ventilated patients with and without mild to moderate ARDS

Published: 26-06-2017
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To study the relation between PaO2/FiO2-ratio and FiO2

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47790

Source
ToetsingOnline

Brief title
The effect of FiO2 on PaO2/FiO2 ratio

Condition

- Other condition

Synonym
PaO2/FiO2 ratio

Health condition

De PaO2/FiO2 ratio wordt bestudeerd

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ARDS, mechanical ventilation, oxygen, PaO2/FiO2 ratio

Outcome measures

Primary outcome

The relationship between FiO2 and PaO2/FiO2-ratio

Secondary outcome

Shunt fraction, arteriovenous oxygen difference and alveolar - arterial oxygen

difference will be determined in these patients to explain the relationship

between FiO2 and the PaO2/FiO2-ratio

Study description

Background summary

The PaO2/FiO2 ratio is frequently used to determine the severity of lung injury in mechanically ventilated patients. However, several mathematical models have shown that PaO2/FiO2 ratio depends on FiO2. The relationship is complex and depends on numerous physiological variables, including shunt fraction, and arterio-venous oxygen difference. The nonlinear relation between PaO2/FiO2 and FiO2 underlines the limitations describing the intensity of hypoxemia using PaO2/FiO2 and is thus of major importance for the clinician. Surprisingly, this relationship has only been assessed mathematically. Obviously, the accuracy of the mathematical relationship depends on the input variables used.
The current study is designed to assess the PaO2/FiO2 vs FiO2 relation in clinical practice.

Study objective

To study the relation between PaO2/FiO2-ratio and FiO2

Study design

An unblinded, prospective, interventional study

Intervention

Two interventions will be performed:
1. Modulation of FiO2: FiO2 will be reduced to 21% or until peripheral oxygen saturation of 92%, whatever occurs first. Subsequently FiO2 will be increased up to 100%.
2. Withdrawal of blood: Blood will be withdrawn from the indwelling arterial line and pulmonary artery catheter. No catheters will be inserted for the study. The maximum number of time points is 7. At each time point 1.5 ml of blood will be withdrawn from both the arterial and pulmonary artery catheter for blood gas analysis. At the start and the end of the study period 2 additional blood samples of 5 ml each will be drawn. Accordingly, the maximum amount of blood obtained will be less than 50 ml.

Study burden and risks

The risk and burden for study subjects is negligible. Blood will be withdrawn from the indwelling arterial line and the pulmonary artery catheter. The insertion of arterial and pulmonary artery catheters are part of standard ICU care. Pulmonary artery catheters will not be inserted just for the purpose of the study. The maximum amount of blood obtained will be less than 50 ml. This limited amount of blood will not result in adverse events for the patients participating. For individual patients no benefits are expected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Mechanically ventilated patients, admitted to the ICU, without ARDS or with mild (200 mmHg < PaO2/FIO2 <=300 mmHg with PEEP >=5 cmH2O) to moderate (100 mmHg < PaO2/FIO2 <=200 mmHg with PEEP >=5 cmH2O) ARDS (according to the Berlin criteria):
• Stable hemodynamics
• Stable haemoglobin level
• Stable body temperature
• Stable level of sedation
• Pulmonary-Artery and Artery catheter

Exclusion criteria

• Incomplete revascularization after CABG
• Cardiac ischemia
• Neurotrauma
• Severe ARDS (PaO2/FIO2 <=100 mmHg with PEEP >=5 cmH2O)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-09-2017
Enrollment:	35
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Conoxia
Generic name:	Oxygen
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	26-06-2017
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	24-07-2017
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	12-10-2017
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	08-06-2018

Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	24-07-2018
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2017-002022-20-NL
ClinicalTrials.gov	NCT03156218
CCMO	NL61945.029.17