Implementation of lower oxygenation targets to improve outcome in ICU patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27410

Source
Nationaal Trial Register

Brief title
Oxytar, Oxygen targets (in ICU patients)

Health condition

High inspiratory oxygen concentrations and high arterial oxygen pressures (PaO2) are independently associated with higher mortality in ICU patients. Although (inter)national guidelines advocate low (physiological) oxygenation targets, ICU-patients in the Netherlands achieve much higher PaO2 values.

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: ZonMw projectnumber: 80-82315-97-12017

Intervention

Outcome measures

Primary outcome

Primary End-points will include an analysis of the process of implementation, specifically the mean proportion (per patient) of PaO2 measurements within target range (primary endpoint), mean PaO2 and FiO2, and mean proportion of PaO2 measurements > 16 kPa (hyperoxia). Additional endpoint is the subjective judgement and appreciation of the guideline and the oxygenation targets by physicians and nurses.

Secondary outcome

Secondary End-points, Outcome: Hospital mortality, ICU-mortality and days alive and without mechanical ventilation at 28 days after ICU admission. Outcome endpoints will be studied in all ICU patients and in a subgroup of patients that had mechanical ventilation at any time during ICU-stay.

Study description

Background summary

Multicenter study to evaluate adherence to lower oxygen targets in ICU patients using a two-phase step-wise implementation strategy. The project will increase the current knowledge as follows:

1. Are the tested implementation strategies successful with respect to adherence to oxygenation targets as recommended?

2. Does introduction of a computerized decision-support module add to the success of implementation?

3. The project will provide new evidence on the effects of implementation of lower oxygenation targets on outcome of patients which may help future large-scale implementation.

Study objective

Aim of this project is to improve adherence to lower oxygen targets in ICU patients using a two-phase step-wise implementation strategy. RESEARCH QUESTIONs are: What are the effects of a stepwise implementation strategy, including a computerized decision-support module, on guideline adherence, outcome and costs of implementation?

Study design

1. April 2012: Start. Retrospective baseline measurement (period: Apr 1st 2011 - Apr 1st 2012);

2. May/June 2012: Introduction of guideline, education, SPC feedback (phase 1);

3. July 1st, 2012: Start data collection first phase of implementation;

4. December 1st, 2013: Phase 2, introduction decision-support application in PDMS. Continuation of measures of implementation;

5. July 1st, 2014: End of study, data analysis;

6. November 1st, 2014: End of project.

Intervention

The study phases:

1. Retrospective: Baseline measurement over 12-months period. They include in-hospital mortality, ICU-mortality, number of days alive and without artificial ventilation at 28 days after ICU admission, PaO2 values, FiO2 values. All data are collected from existing databases (PDMS and NICE). Severity of illness, using the APACHE IV and SAPS II model, is retrieved for all patients from the National Intensive Care Evaluation (NICE) database;

2. First implementation phase. This phase will consist of providing a written guideline with clear recommendations how to adapt oxygen administration and ventilator settings depending on arterial blood gas measurements. It will include repeated education on the background of lower oxygenation targets (potential oxygen toxicity, international recommendations, present situation with non-adherence to recommendations, safety of lower oxygenation targets) and on actions to be taken to adhere to the guideline. It includes a clear description of preferred PEEP/FiO2 combinations. We will provide continuous process feedback by statistical process control (SPC), and involvement of local leadership to promote a culture that support adherence to the guideline (for more information: see section implementation). After a 3-months wash-in period, data will be collected over the subsequent 6 months. De same data will be collected as in the baseline measurement;

3. Introduction decision-support. The decision-support will be based on exactly the same targets as the guideline from phase 2 and will work in the active, critiquing mode, meaning that it will give decision-support without being asked for but only if the actual situation is not according to the guideline. A pop-up window will appear in the patient data management system if PaO2 is higher than recommended. It will suggest to adapt oxygen administration and/or ventilator settings based on collected arterial blood gas measurements. Actual decisions to change these settings will be made by nurses and physicians in the ICU. Measures from the first phase of implementation will be continued with continuous feedback and repeated education. Data will be collected after a 6-weeks wash-in period. Duration of data-collection is 6 months.

23-aug-2014 changes:
Phase 2: Data was collected over the subsequent 12 months (instead of 6 months).

Phase 3: Addition of "repeated SpO2 measurements" to "A pop-up window will appear in the patient data management system if PaO2 or repeated SpO2 measurements is/are higher than

recommended.

Contacts

Public
PO-box 9600
Evert Jonge, de
Dept of Intensive Care
Leiden University Medical Center
B04Q-room 057
Albinusdreef 2
Leiden 2300 RC
The Netherlands
+31 (0)71 5265018
Scientific
PO-box 9600
Evert Jonge, de
Dept of Intensive Care
Leiden University Medical Center
B04Q-room 057
Albinusdreef 2
Leiden 2300 RC
The Netherlands
+31 (0)71 5265018

Eligibility criteria

Inclusion criteria

All ICU patients admitted during the studyperiod at 3 ICUs, with subgroup analysis in all patients on mechanical ventilation.

Exclusion criteria

Patients on extracorporeal membrane oxygenation (ECMO).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2012
Enrollment:	10000
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	07-05-2012
Application type:	First submission

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
NTR-new	NL3271
NTR-old	NTR3424
Other	METC LUMC : C12.045
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
Helmerhorst HJ, Schultz MJ, van der Voort PHJ, Bosman RJ, Juffermans NP, de Jonge E, van Westerloo DJ. Self-reported attitudes versus actual practice of oxygen therapy by ICU nurses and physicians. Annals of Intensive Care 2014, 4:23
http://www.annalsofintensivecare.com/content/4/1/23