Arterial oxygenation targets in Intensive Care patients

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To compare a ventilation strategy that uses conservative targets (PaO2 55-80 mmHg (7.3-10.7 kPa)) with one that uses conventional oxygenation targets (PaO2 110-150 mmHg (14.7-20 kPa)) for arterial oxygenation. Primary endpoint is all-cause mortality...

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19970

Bron
Nationaal Trial Register

Verkorte titel
ICONIC

Aandoening

Intensive Care patients
Mechanical ventilation
Oxygenation targets

Ondersteuning

Primaire sponsor: Leiden University Medical Centre
Overige ondersteuning: ZonMw (Zorgonderzoek-Medische Wetenschappen)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

All-cause mortality on day 28 after randomisation

Toelichting onderzoek

Achtergrond van het onderzoek

Oxygen therapy is a widely used intervention in intensive care unit (ICU) patients. However, supraphysiological oxygenation may have harmful effects, especially during prolonged exposure. Several studies, including investigations from the Netherlands, have demonstrated a clear association between high arterial oxygen levels and increased mortality in ICU patients. Despite this accumulating evidence it remains unclear which arterial oxygenation targets to adher to for the highest survival. In this trial we aim to compare low normal (conservative) and high normal (conventional) oxygenation targets in Intensive Care patients.

Doel van het onderzoek

To compare a ventilation strategy that uses conservative targets (PaO2 55-80 mmHg (7.3-10.7 kPa)) with one that uses conventional oxygenation targets (PaO2 110-150 mmHg (14.7-20 kPa)) for arterial oxygenation. Primary endpoint is all-cause mortality at 28 days after ICU-admission.

Onderzoeksopzet

Patients in participating intensive care units (ICU) will be screened for inclusion. Eligible patients will be randomised within 2 hours of start of mechanical ventilation. Informed consent will be obtained if possible prior to start of intervention. However, in the majority of the cases inclusion will take place in an emergency setting when the patient is incapacitated and in those cases deferred consent will be obtained as soon as possible, preferably within 72 hours after randomisation. Demographic data on screened patients regardless of meeting enrolment criteria will be recorded (registry: age, gender, admission type, organ failure and comorbidities).

At least one blood gas analyses per shift (three per 24 hours) will be required whilst mechanically ventilated. Daily evaluation registered in the eCRF will include ventilator mode and settings, delirium, and arterial blood gas and laboratory evaluation, whereby SOFA-scores will be calculated. When a study endpoint is reached transfusion of blood products, and events of bloodstream- and respiratory tract infection, surgical site infection, and ischemia will be evaluated and recorded.
Follow up will include hospital and 90-day mortality, which will be recorded. Furthermore, at 6 and 12 months patients will receive a quality of life and patient opinion about research and consent in the emergency setting questionnaire.

The investigator can decide to deviate from the study protocol for a subject for urgent medical reasons, such as ARDS with a PaO2/FiO2 ratio less than 150 mmHg. These patients

will not be withdrawn from the study and will be analysed according to the intention-to-treat principle.

Onderzoeksproduct en/of interventie

The conservative oxygenation arm will be targeted at PaO2 55-80 mmHg (7.3-10.7 kPa) and/or SpO2 91-94% and the conventional oxygenation arm will be targeted at PaO2 between 110-150 mmHg (14.7-20 kPa) and/or SpO2 >96%.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age ≥ 18 years

Admission to an ICU participating in this study Need for intubation and mechanical ventilation

An expected mechanical ventilation time of 24 hours or longer

Inclusion within 2 hours after start of invasive ventilation in the study ICU or if previously intubated and ventilated within 2 hours after admission to the study ICU

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Readmitted to the intensive care unit and prior ICONIC inclusion

Invasive ventilation longer than 12 hours directly preceding admission

Participation in other interventional trials which could influence ICONIC intervention and/or endpoints

Suspected or confirmed pregnancy

Decision to withhold life-sustaining treatment at the time of inclusion

Acute respiratory distress syndrome (ARDS) with a PaO2/FiO2 ratio less than 150 mmHg

Acute decompensation of chronic obstructive pulmonary disease(COPD) and/or chronic hypoxaemia and/or use of home oxygen therapy

Underlying disease indication for hyperoxygenation (for example: carbon monoxide intoxication, decompression sickness, gas embolism)

Severe anaemia (Hb< 4.0 mmol/l) that is not rapidly reversible (e.g. if blood transfusions are not possible or not allowed for religious reasons)

Uncontrollable intracranial hypertension

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestart

(Verwachte) startdatum:	19-11-2018
Aantal proefpersonen:	1512
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55692
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7185
NTR-old	NTR7376
CCMO	NL65236.058.18
OMON	NL-OMON55692

Resultaten