Insufficient cellular oxygen in ICU patients with anaemia: the INOX ICU-2 Study

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1. To determine the feasibility and variability of mitoPO2 measurement in critically ill intensive care unit (ICU) patients who are about to receive a transfusion 2. To describe the effects of red cell transfusion and the associated change in [Hb]...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON50343

Source
ToetsingOnline

Brief title
the INOX ICU-2 Study

Condition

- Other condition

Synonym
anaemia, anemia

Health condition

anemie bij kritisch zieke mensen op de IC

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Sanquin Research

Intervention

Keyword: anemia, mitochrondial oxygenation, transfusion

Outcome measures

Primary outcome

The primary endpoint is the variability of mitoPO2 before and after red cell transfusion. This will be compared to traditional parameters used to measure oxygenation and oxygen balance(ScvO2, SaO2, PaO2, PvO2, CI, lactate). Another primary endpoint is the value of mitoPO2 measurements for predicting (ischemic) organ damage. The following parameters for organ damage (that are routinely collected) will be assessed: lung (pO2/FiO2 ratio), heart (troponin, CK, an ECG, CI), renal (creatinine, urine production, glomerular filtration rate, RIFLE classification), brain (delirium, RASS) and SOFA score.

Secondary outcome

Secondary study parameters include:

- Length of ICU stay

- Length of stay in hospital

- Hospital mortality

- ICU mortality

- 90 day mortality

- Adverse and serious adverse events of the mitoPO2 measurements

- Need for mechanical ventilation

- Need for renal replacements therapy

- Microcirculatory value of mitoPO2

- Possible bias of mitoPO2 measurements (skin temperature, vasopressor use,

inotropic therapy)

Study description

Background summary

Depending on the duration of critical illness eventually all critically ill patients develop anaemia which may severely affect their recuperation. Deleterious effects of severe anaemia include a generalized decrease in oxygen carrying capacity and ensuing multi-organ failure. The notion that critically ill patients with [Hb] above 7 or 8 g/dl, might not profit from red cell transfusions has been confirmed by many other studies and is now widely adopted in clinical guidelines. Yet, there is also increasing evidence that in some cases a [Hb] transfusion trigger of 7- 8 g/dl may be too low. Whether these findings are solid enough to change clinical practice is heavily debated. These uncertainties about efficacy and safety of transfusion lead to undesirable ambiguities in ICU transfusion practice.
Dr. Bert Mik has recently introduced the protoporphyrin IX-triplet state lifetime technique as the first method to measure mitochondrial oxygen tension (mitoPO2) in living cells and tissues. The mitoPO2 measurement was able to predict the need for a red cell transfusion in animal models and in healty volunteers. However, the predictibility of transfusion of critical ill patients hasn't been studied yet. We hypothesize that mitoPO2 can be used as an early indicator of organ dysfunction as well. If this is true, mitoPO2 can possibly be used to administer or postpone red cell transfusion in patients with anaemia.

Study objective

1. To determine the feasibility and variability of mitoPO2 measurement in critically ill intensive care unit (ICU) patients who are about to receive a transfusion 2. To describe the effects of red cell transfusion and the associated change in [Hb] on mitoPO2 and on other physiologic measures of tissue oxygenation and oxygen balance 3.To describe the association between mitoPO2 and vital organ functions

Study design

Prospective multicenter cohort study

Study burden and risks

The risks are neglible in this study with no SAE known. The burden for the ICU-patients is minimal since it*s a non-invasive measurement. The normal clinical practice will continue and will not be altered with. Since most ICU-patients are in the most controlled environment with a central venous catheter and arterial catheter in situ, they are the most ideal patient to investigate mitoPO2 feasibility, accuracy and associations with other physiological parameters.
This is the very first research on mitoPO2*s clinical applicability in critically ill patients with anaemia and the first attempt to personalize blood transfusion decisions in the ICU based on individual assessment of the ability of oxygen transport to tissue to fulfill actual oxygen utilization. We hypothesize that mitoPO2 can be used as an early indicator of organ dysfunction as well. If this is true, mitoPO2 can possibly be used to administer or postpone red cell transfusion in patients with anaemia.

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

During the pilot study: all adult patients, admitted to the intensive care unit with [Hb] below 6,3 mmol/l, who are planned to undergo a transfusion of red blood cells.
During the prospective cohort study: all patients with a Hb below 6.3 mmol/l in whom an arterial catheter is in place and in whom a red cell transfusion is planned.

Exclusion criteria

-adults without an legal representative for the informed consent,
-less than 18 years old,
-patients in need of emergency red cell transfusion e.g. bleeding,
-porphyria,
-known photodermatosis,
-ICU stay <24hrs,
-pregnant or breast feeding women since there is no adequate data from the use of ALA in pregnant or breast feeding women,
-hypersensitivity to the active substance or to the plaster material of ALA,
-insufficient comprehensibility of the Dutch language

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-05-2017
Enrollment:	209
Type:	Actual

Medical products/devices used

Generic name:	COMET measurement system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	03-04-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	06-10-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	21-02-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	11-03-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
ClinicalTrials.gov	NCT03092297
CCMO	NL59512.058.16