Insufficient oxygenation in septic patients: the INOX Sepsis Study

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1. To describe mitoPO2 in clinically admitted critically ill septic patients receiving fluid therapy (consisting of crystalloid, albumin and/or red cell transfusion).2. To describe the effects of fluid therapy on mitoPO2 and on other physiological...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON55764

Source
ToetsingOnline

Brief title
the INOX Sepsis Study

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
blood poisoning, sepsis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: mitochondrial oxygenation, sepsis

Outcome measures

Primary outcome

Change in mitoPO2 before and after fluid therapy. This will be compared to traditional parameters used to measure oxygenation and oxygen balance

Secondary outcome

Secondary endpoints:

- Association of mitoPO2 change with separate (ischemic) organ (dis)function and the SOFA score after 24 hours

- Safety of mitoPO2 measurements in critically ill septic patients

- Description of the association between mitoPO2 change and clinical outcomes, like length of stay (both ICU and in-hospital) and mortality (both ICU and in-hospital)

- Association between mitoPO2 and severity of sepsis to immune parameters such as plasma cytokines and cellular phenotypes.

- Description of the level of hypoxia, including mitoPO2, in critically ill patients with sepsis due to COVID-19.

Study description

Background summary

Evidence is increasing that there is no clear parameter for tissue oxygenation in critically ill septic patients to guide resuscitation. New studies have shown the potential of protoporphyrin IX-triple state lifetime technique to measure mitochondrial oxygenation tension (mitoPO2) in vivo, which possibly is

an early indicator of oxygen disbalance in the cell and therefore a physiological trigger for fluid therapy.

Study objective

1. To describe mitoPO2 in clinically admitted critically ill septic patients receiving fluid therapy (consisting of crystalloid, albumin and/or red cell transfusion).
2. To describe the effects of fluid therapy on mitoPO2 and on other physiological measures of tissue oxygenation and oxygen balance
3. To describe the association between (change of)mitoPO2 and vital organ (dis)functions separately, and 24 hours SOFA score
4. To describe the association between mitoPO2 change and clinical outcomes, like length of stay (both ICU and in-hospital) and mortality (both ICU and in-hospital)
5. To describe the association between mitoPO2 and severity of sepsis to immune parameters such as plasma cytokines and cellular phenotypes.
6. To describe the level of hypoxia, including mitoPO2, in critically ill patients with sepsis due to COVID-19.

Study design

Prospective multi-center cohort study

Study burden and risks

The risks are minimal in this study with no serious adverse events known. The burden for the septic patients is minimal since it*s a non-invasive measurement. The normal clinical practice will continue and will not be altered.

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

- Age of patient is at least 18 years
- Patients diagnosed with sepsis in the emergency department or hospital ward, including patients with possible COVID-19
- Patients are admitted to the ICU via the hospital ward or emergency department
- Informed or deferred consent is given either by the patient or if the patient is too ill to give informed consent, by his or her legal representative
- Patients have an arterial catheter in situ, since blood samples will be taken for the study. Most patients admitted to the ICU have an arterial catheter in place since it is part of standard care.

Exclusion criteria

-Patients younger than 18 years
-Patients with sepsis discharged after emergency department visit
-Patients admitted with sepsis to a hospital ward other than the ICU after emergency department visit
-Patients without a legal representative will be excluded since no informed consent can be given
-Patients known with porphyria and/or photodermatosis will be excluded, due to the risk of phototoxicity
-Patients with hypersensitivity to the active substance or to the plaster material of ALA (5-aminolevulinic acid)
-Pregnant or breast feeding women since there is no adequate data form the use of ALA in pregnant or breast feeding women

-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):	01-03-2019
Enrollment:	90
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	16-01-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	06-05-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	26-06-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	22-12-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	12-07-2021
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	NCT03842722

Register	ID
CCMO	NL64824.058.18

Study results

Date completed:	28-07-2023
Actual enrolment:	72

Summary results
Trial ended prematurely