# Mitochondrial oxygen measurement variability in critically ill patients: Validation of the COMET measurement system

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To describe the between- and within-subject variability of mitoPO2 measurements during a 24 hour period after 5- aminolevulinic acid (ALA)-induction among healthy volunteers and among neurosurgical patients admitted postoperatively to the ICU, MC,...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Neurological disorders NEC |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON54934

**Source**
ToetsingOnline

**Brief title**
INOX variability study

### Condition

- Neurological disorders NEC

**Synonym**
brain surgery, neurosurgery

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Sanquin Research

## Intervention

**Keyword:** measurement variability, mitochondrial oxygenation

## Outcome measures

### Primary outcome

Between- and within-subject variability (assessed by standard deviation) of

mitoPO2 measurements over a period of 24 hours after ALA-induction.

- Initially in healthy volunteers

- Followed by neurosurgical patients admitted postoperatively to the ICU or MC,

PACU or other hospital ward.

### Secondary outcome

Secondary endpoints:

- Description of the differences in the between- and within-subject variability

between 3 hour offset ALA-patches.

- Description of between- and within-subject variability in healthy volunteers

and neurosurgical patients in relation to the between- and within-subject

variability of the INOX ICU-2 pilot study (NL59512.058.16)

- Report on adverse and serious adverse events of the mitoPO2 measurements.

# Study description

### Background summary

Recent studies have shown the potential of a protoporphyrin IX-triple state lifetime technique to measure mitochondrial oxygen tension (mitoPO2) in vivo, which possibly is an early indicator of oxygen disbalance in the cell. With the advent of the COMET measurement system, steps have been made to determine the

feasibility of this measurement method. The INOX ICU-2 study (parent study) aims to tailor transfusion therapies to individual ICU patients based on mitochondrial oxygen tension. In the pilot study of the INOX ICU-2 study, in which the COMET measurement system was used on critically ill patients receiving red blood cell transfusion, an increase in the between- and within-subject variability was observed over time. This deviation was not explored during the development of the COMET measurement system. Therefore, we aim to determine the between- and within-subject variability of this measurement in healthy subjects and in hemodynamically stable subjects at the intensive care unit.

### Study objective

To describe the between- and within-subject variability of mitoPO2 measurements during a 24 hour period after 5- aminolevulinic acid (ALA)-induction among healthy volunteers and among neurosurgical patients admitted postoperatively to the ICU, MC, PACU or other hospital ward. Healthy subjects allow for the exploration of the effect of time-since-application of ALA-patch and neurosurgical patients allow for the exploration of a possible effect of (ICU-) admittance.

### Study design

Prospective cohort study

### Study burden and risks

The risks are small in this study with no serious adverse events (SAE) known. The burden for participants is small since it involves a non-invasive measurement. We will perform this study first in health volunteers. Following the healthy volunteers, neurosurgical patients will be included. Patients will undergo neurosurgery as planned and common practice is that no major interventions are needed in the postoperative phase on the ICU, PACU or orther hospital ward. Normal clinical practice will continue and will not be altered. These patients will allow for the exploration of a possible effect of (ICU) admittance.

## 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

Patients meeting all these criteria will be included in the study:
• Age of patient is at least 18 years
• Healthy participants, defined as the absence of active or chronic disease (applicable only to healthy volunteer group).
• Patients are admitted to the intensive care unit, medium care, PACU or other hospital ward after neurosurgery (applicable only to neurosurgery group).

## Exclusion criteria

Patient meeting one of these criteria will be excluded from the study:
• pregnant or breast feeding women since there is no adequate data from the use of ALA in pregnant or breast feeding women
• patients with porphyria and/or known photodermatosis
• patients with 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

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 14-07-2020 |
| Enrollment: | 34 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Generic name: | Comet measurement device |
| Registration: | Yes - CE intended use |

# Ethics review

Approved WMO

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|---|---|
| Date: | 24-04-2020 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

Approved WMO

| | |
|---|---|
| Date: | 26-11-2020 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

Approved WMO

| | |
|---|---|
| Date: | 02-04-2021 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>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 | NCT04626661 |
| CCMO | NL71914.058.19 |