Anaesthetic management guided by cellular oxygen metabolism measurements

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The primary objective of this pilot trial is to evaluate if adding mitoPO2 monitoring to standard anaesthetic management enables tissue oxygenation optimisation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON51147

Source
ToetsingOnline

Brief title
AIMED COMET pilot trial

Condition

- Bacterial infectious disorders
- Gastrointestinal therapeutic procedures

Synonym
surgical site infection, surgical wound infection

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Photonics Healthcare BV KvK 30243951

Intervention

Keyword: Anaesthetic management, Cellular oxygen metabolism, Mitochondrial oxygenation tension, Perioperative care

Outcome measures

Primary outcome

The primary outcome is the mean mitoPO2 over time.

Secondary outcome

Secondary outcomes are the number of incidences that mitoPO2 aids decision-making on anaesthetic management, the proportion of these incidences that were associated with a change in mitoPO2 or a change in mitoPO2 slope and the proportion of patients this occurs in, the type of interventions used to improve mitoPO2 and their respective effect, the average cumulative duration of mitoPO2 below individual baseline value, the association of mitoPO2 with conventional hemodynamic monitoring measures and the SSI incidence after 30 days follow-up.

Study description

Background summary

Surgical site infection (SSI) is one of the most common healthcare-associated infections (HAIs) and a significant cause of morbidity and mortality, prolonged hospital stays and healthcare costs. Perioperative low tissue oxygen tension (tPO2) is associated with a high risk of SSI. Continuous monitoring of oxygen delivery (DO2) with a non-invasive method of measuring mitochondrial oxygenation tension (mitoPO2) using the COMET (Cellular Oxygen METabolism) monitor may benefit the intraoperative oxygenation on the tissue level, potentially reducing the incidence of SSI.

Study objective

The primary objective of this pilot trial is to evaluate if adding mitoPO2 monitoring to standard anaesthetic management enables tissue oxygenation optimisation.

Study design

Randomised controlled patient-blinded parallel-group multicentre pilot trial.

Intervention

Intraoperative monitoring and optimisation of DO2 using the COMET in addition to standard anaesthetic management.

Study burden and risks

The subjects receive usual care and do not require deviation from standard protocol, regardless of their allocation. The COMET*s intraoperative non-invasive measurements are regarded as safe and do not result in any increased risk. The 5-aminolevulinic acid (5-ALA) medicated plaster is widely used in Actinic Keratosis (AK) treatment and is generally accepted. Patients will be subjected to regular follow-up, which does not deviate from usual care. Overall risks are considered negligible and the burden low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

Patients are at least 18 years old
Patients undergo elective open or laparoscopic abdominal surgery
Patients are able and willing to give written informed consent

Exclusion criteria

Known photodermatoses of varying pathology and frequency
Mitochondrial disease
Porphyria
Hypersensitivity to the active substance or to the 5-ALA medicated plaster material
Emergency surgery
Re-operation for complications from recent surgery (within last three months)
Participation in another study with interference with this study
Pregnancy or breast-feeding

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-09-2021
Enrollment:	98
Type:	Actual

Ethics review

Approved WMO

Date:	05-08-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29588
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL77186.018.21
OMON	NL-OMON29588