Anaesthetic management guided by cellular oxygen metabolism measurements

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We hypothesise that standard anaesthetic management guided by mitoPO2 monitoring to optimise tissue oxygenation, using conventional measures, results in higher tPO2 during surgery and, therefore, a higher mean mitoPO2 over time.

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

Samenvatting

ID

NL-OMON29588

Bron
NTR

Verkorte titel
AIMED COMET pilot trial

Aandoening

Adult patients undergoing elective open or laparoscopic abdominal surgery.

Ondersteuning

Primaire sponsor: Amsterdam University Medical Centres, Location AMC
Overige ondersteuning: Photonics Healthcare B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Mean mitoPO2 during abdominal surgery over time

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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. Standard anaesthetic management guided by 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.

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

Study design: Randomised controlled patient-blinded parallel-group multicentre pilot trial.

Study population: Adult patients undergoing elective open or laparoscopic abdominal surgery.

Intervention: Standard anaesthetic management guided by mitoPO2 monitoring.

Main study parameters/endpoints: The primary outcome is the mean mitoPO2 during abdominal surgery over time. Secondary outcomes are the number, type and the respective effect of interventions that results in an increase of mitoPO2 after notification in which mitoPO2 aids decision making on anaesthetic management, the proportion of these incidences that were associated with a change in mitoPO2 and the proportion of patients this occurs in, 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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Doel van het onderzoek

We hypothesise that standard anaesthetic management guided by mitoPO2 monitoring to optimise tissue oxygenation, using conventional measures, results in higher tPO2 during

surgery and, therefore, a higher mean mitoPO2 over time.

Onderzoeksopzet

- Mean mitoPO2 during abdominal surgery over time with the COMET monitor; it is measured with the COMET, starting at the moment of surgery until the end of surgery
- Number, type and the respective effect of interventions that results in an increase of mitoPO2 after notification in which mitoPO2 aids decision making on anaesthetic management: it is measured with the COMET, starting at the moment of surgery until the end of surgery. The number and type of interventions will be tracked by the researcher.
- The proportion of these incidences that were associated with a change in mitoPO2 and the proportion of patients this occurs in: the proportion is based on the incidences during surgery and will be calculated during the data analysis.
- The average cumulative duration of mitoPO2 below individual baseline value; it is measured with the COMET, starting at the moment of surgery until the end of surgery.
- The association of mitoPO2 with conventional hemodynamic monitoring measures; it is tracked within EPIC and will be investigated during the data analysis.
- The SSI incidence after 30 days follow-up; according to the CDC definition, as prospectively registered by ward doctors, through medical chart review

Onderzoeksproduct en/of interventie

Standard anaesthetic management guided by mitoPO2 monitoring.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Patients are at least 18 years old
• Patients undergo elective open or laparoscopic abdominal surgery with an expected minimal total incision size of 5 cm
• Patients are able and willing to give written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Known photodermatoses of varying pathology and frequency
• Mitochondrial disease
• Porphyria
• Skin lesions on the upper arm which impede measurements
• Hypersensitivity to the active substance or the 5-ALA medicated plaster material
• Emergency surgery
• Reoperation for complications from recent surgery (within last three months)
• Participation in another study with interference with this study
• Pregnancy or breastfeeding

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	02-08-2021
Aantal proefpersonen:	98
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 51147
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9505
CCMO	NL77186.018.21
OMON	NL-OMON51147

Resultaten