Clinical Observational Study into Mitochondrial Oxygenation Predicting Ominous Lactate In Trajectory around Abdominal Surgery

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Cutaneous mitochondrial oxygen tension measurements are correlated with serum lactate measurements.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28542

Bron
NTR

Verkorte titel
COSMOPOLITAS

Aandoening

Liver disease

Ondersteuning

Primaire sponsor: Not applicable
Overige ondersteuning: Industry

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- MitoPO2 (mmHg) measured semi-continuously peri-operatively and during 48 hours post-operatively using the automated setting of the COMET-device
- Lactate levels (mmol/l) measured four times per 24 hours

Toelichting onderzoek

Achtergrond van het onderzoek

Lactate is produced during anaerobic metabolism and is commonly used as a marker for inadequate tissue perfusion. As studies show that even a small rise in lactate levels is associated with increased morbidity and mortality, therapy strategies have been based on increasing lactate clearance and reducing lactate levels. Since lactate changes take place over hours, a more sensitive monitoring parameter has been long sought after. Previous studies have shown the potential of the recently introduced Cellular Oxygen METabolism (COMET) monitor (Photonics Healthcare, Utrecht), which measures cutaneous mitochondrial oxygen tension (mitoPO2) and oxygen consumption (mitoVO2).This study will provide the base for future studies which investigate whether mitochondrial oxygen monitoring can predict changes in serum lactate and if it can be used as a tool for optimizing hemodynamic management.

Doel van het onderzoek

Cutaneous mitochondrial oxygen tension measurements are correlated with serum lactate measurements.

Onderzoeksopzet

- On admission to the clinical ward the day before surgery the researcher will visit the patient and two ALA-plasters will be placed on the upper arm/shoulder.
- Health status will be checked according to the pre-operative form, medication use and medical history.
- The measurements will be started before induction. The mitoPO2 shall be measured in intervals and measurements will continue up until 48 hours post-operatively or until available. Lactate measurements will be performed four times per 24 hours, adhering to standard care protocol as much as possible.
- Capillary refill and delta temperature will be derived from the medical dossier when performed by hospital personnel. Alternatively, delegated study personnel will measure core and skin temperature and test capillary refill four times per 24 hours.
- After 48 hours the probe will be removed and the skin exposed to ALA will be covered with a light-shielding plaster for 24 hours.
- The local site of the plasters will be checked 24 hours after the plaster in question has been removed.
- Clinical outcome and complications will be checked after one month in the electronic patient dossier

- Patients will be called two weeks after discharge by the researcher to gain feedback about their experiences during the study period. This will include feedback on the measurements, adherence of the COMET Sensor Holder to their arm for 48 hours post-operatively and if they have experienced any adverse events after their discharge out of the hospital.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age over 18 years
Acceptable proficiency of the Dutch language
Scheduled for major abdominal surgery, the primary focus will be on liver resection and liver transplantationsurgery
Written informed consent has been signed prior to or on admission to the surgical ward before surgery

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Presence of mitochondrial disease
Pregnancy/lactation
Patients with skin lesions on upper arm/shoulder which impede measurements

Porphyria
Known intolerance to components of the ALA plaster
Patients uncapable of providing informed consent, due to a mental condition interfering with the ability tounderstand the provided information

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	25-03-2021
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	22-07-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49214
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9632
CCMO	NL74651.078.20
OMON	NL-OMON49214

Resultaten