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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28542

Source
NTR

Brief title
COSMOPOLITAS

Health condition

Liver disease

Sponsors and support

Primary sponsor: Not applicable
Source(s) of monetary or material Support: Industry

Intervention

Outcome measures

Primary outcome

- 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

Secondary outcome

- Feasibility and accuracy of COMET measurements in an awake population during a 48 hr post-operative trajectory will be judged based on signal quality of the measurements during this period and the experiences of the researchers and patients
- The capability of the 5-ALA patch to provide 5-ALA which will be metabolized into PpIX for the purpose of fluorescence-based measurements
- Experience of patients regarding the ALA-plasters, COMET Sensor Holder and measurements, collected during a telephone call two weeks after their hospital admission
- Laboratory values (hemoglobin mmol/l, ALAT U/l, ASAT U/l and creatinine umol/l)
- Urine production and fluid balance during ICU/PACU admission
- Standard hemodynamic parameters, such as blood pressure (mmHg), peripheral perfusion index, heart rate (bpm) and oxygen saturation (%)
- Clinical outcome, such as length of ICU stay, length of hospital stay
- Post-operative complications, especially wound infection and impaired kidney function
- The effect of time interval on signal quality
- Delta temperature
- Capillary refill in seconds

Study description

Background summary

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.

Study objective

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

Study design

- 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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-03-2021
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	22-07-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49214
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results