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

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Primary objectives: - To test the hypothesis that a relationship between mitochondrial oxygenation and serum lactate existsSecondary objectives:- To provide data for estimating the number of patients needed for a clinical trial to prove the above...

Ethical review	Approved WMO
Status	Completed
Health condition type	Hepatobiliary therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON49214

Source
ToetsingOnline

Brief title
COSMOPOLITAS

Condition

- Hepatobiliary therapeutic procedures

Synonym
hepatectomy, large abdominal surgery, liver surgery, liver transplantation

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Photonics Healthcare

Intervention

Keyword: Lactate, Mitochondria, Oxygen, Surgery

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

- Arterial lactate levels (mmol/l) measured four times per 24 hours or until available

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 will be evaluated by the signal quality of the mitoPO2 measurements after prolonged hours of measurements, defined as over 24 hours of measurements. This can be evaluated without involvement of the patient.

- Adverse events will be monitored throughout the study period. Special attention will be attenuated to the plaster site by daily investigation.
Subjects will be asked if any physical discomfort has taken place and their overall experience.

- 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) are sampled according to standard care

- Urine production and fluid balance during ICU/PACU admission, measured during standard care will be registered

- Throughout the operation and the first 24 hours on the ICU, standard hemodynamic parameters, such as blood pressure (mmHg), heart rate (bpm) and oxygen saturation (%) are recorded every minute during the operation and every 15 minutes on the ICU. On the ward they are measured and recorded three times a day.

- Clinical outcome, such as length of ICU stay, length of hospital stay

- Post-operative complications, especially wound infection and impaired kidney function. Kidney function will be based on serum creatinine and urine production

- The effect of time interval on signal quality will be judged based on signal quality of measurements with different time-intervals

- Delta temperature (measured non-invasively, using core temperature (e.g. tympanic) and skin temperature), capillary refill

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 (Phototonics 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

Primary objectives:
- To test the hypothesis that a relationship between mitochondrial oxygenation and serum lactate exists

Secondary objectives:
- To provide data for estimating the number of patients needed for a clinical trial to prove the above mentioned relationship and/or its clinical significance.
- To test the feasibility and accuracy of COMET-measurements in an awake population during a 48 hr post-operative trajectory.
-To observe the duration of acceptable measurements after using a single plaster. Acceptable measurements are defined as measurements with a signal quality of at least 20%.
-To observe adverse events related to the prolonged usage of aminolevulinic acid plasters in combination with the COMET-measurement device.
-To observe the relation between low mitochondrial oxygen tension in the skin and post-operative outcome, especially wound infections and kidney function.
- To provide information on relevant clinical parameters associated with tissue hypoxia, fluid balance and liver function

Study design

Single center observational pilot study

Study burden and risks

The intracellular oxygen measurements performed by the COMET are non-invasive and do not require deviation from standard protocol. Mild possible physical discomfort may arise from use of the aminolevulinic acid plaster or the armpiece (COMET Sensor Holder) which will be attached to the arm during the study period. All patients will receive an arterial catheter on the day of the operation, placed by skilled personnel. Arterial blood sampling via the arterial catheter will be performed four times per 24 hours, adhering to standard care as much as possible. The sampling is painless and does not cost the patient extra time. After discharge to the clinical ward, the time point

where standard of care requires removal of the arterial line, further blood lactate analysis will be performed using arterial needle punctures. This sampling strategy can cause discomfort, but serious complications are rare. Overall the risks are considered negligible and the burden low.

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

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 transplantation surgery
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 to understand the provided information

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	25-03-2021
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	COMET
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	15-12-2020

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-03-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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: 28542
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL74651.078.20
OMON	NL-OMON28542