Tissue oxygenation and perfusion and the determination of glucose subcutaneously

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON34018

Source
ToetsingOnline

Brief title
TOP DOGS

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Cardiac therapeutic procedures

Synonym
glucose metabolism

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: European Foundation for the Study of

Diabetes (EFSD)

Intervention

Keyword: continuous glucose monitoring, Intensive Care Unit, microcirculation

Outcome measures

Primary outcome

Difference in glucose values (mmol/l) measured by the two CGMs, Guardian RT and FreeStyle Navigator compared to *gold standard* blood glucose values measured by the Accu-Chek Compact plus (mmol/l), expressed as mean absolute difference (MAD) of glucose values.

Secondary outcome

1. Microcirculatory function expressed as % of perfused vessels as measured by OPS.

2. Microcirculatory function expressed as microvascular flow index (MFI) as measured by OPS.

3. Tissue oxygen saturation (StO2) expressed as ratio oxygenated haemoglobin to total haemoglobin as measured by near infrared spectroscopy (NIRS).

4. Systemic oxygen saturation (SpO2) expressed as % as measured by pulse oximetry.

5. APACHE II score.

6. SOFA score.

7. Glucose values expressed as mmol/l as measured by the Accu-Chek Compact plus.

Study description

Background summary

Maintaining normoglycemia during intensive care admittance reduces mortality and morbidity. Continuous subcutaneous glucose monitoring (CGM) is regarded as a promising tool in the treatment of diabetes mellitus, even more now that the first real time devices have become available, equipped with alarm function to indicate hyper- and hypoglycemia. No intervention studies have been performed using CGM measurements for clinical decision making in severely ill patients. As CGM depends on the glucose concentration in the interstitial fluid, one could expect the accuracy of CGM is compromised in severely ill patients, because tissue oxygenation and perfusion is altered. There have been studies correlating CGM values with plasma glucose values in the intensive care unit (ICU). These studies report correlation coefficients of 0.74-0.95. No separate analyses have been performed to analyze possible causes of low performance of CGM devices in the ICU. Before CGSM can be implemented in the ICU for intensive insulin therapy (IIT), the relation between tissue perfusion and oxygenation and accuracy of CGM has to be investigated.

Study objective

The main goal of this study is to investigate the performance of two CGM devices, FreeStyle Navigator® CGM system and Guardian® RT in relation to the subcutaneous microcirculatory perfusion (as measured by the orthogonal polarization spectral imaging technique sublingually and near infrared spectroscopy of the right thenar eminence), severity of disease (defined by APACHE II and SOFA scores) and tissue oxygenation (as measured by pulse oximetry).

Study design

The two CGM devices will be inserted and calibrated before surgery and will be taken off 48 hours after surgery or earlier if patients are discharged from the ICU within 48 hours. After surgery, every six hours OPS measurements will be performed as well as the scoring of tissue oxygenation, mean arterial pressure, heart rate, temperature and the use of vasoactive medication. Every hour, glucose is measured with an arterial blood gas analyzer. Every day, SOFA and APACHE II scores will be obtained and assessed whether the patient is septic.

Study burden and risks

The risk for participants is judged to be minor. The insertion and wearing of the sensors is minimally invasive. Two extra venous blood samples of 10ml will be obtained besides standard care samples. The patient may benefit from the

sensor measurements because due to the frequent glucose measurements the strict bloodglucose regulation can be facilitated.

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

Willing and able to give written informed consent
admittance to the OLVG for elective open cardiac surgery (coronary artery bypass graft [CABG]; mitral-, tricuspidal- and aortic valve surgery)
age 18-85 years

Exclusion criteria

abdominal abnormalities that inhibit sensor insertion

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2009
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	20-04-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL25899.100.08