Point and Trend Accuracy of a Continuous Glucose Measurement System using Intravenous Microdialysis in Critically Ill Patients

No registrations found.

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

Summary

ID

NL-OMON27403

Source
NTR

Brief title
ACSI

Health condition

Blood glucose, Monitoring, Critically ill patients

Sponsors and support

Primary sponsor: Academic Medical Center (AMC, Amsterdam)
Source(s) of monetary or material Support: Academic Medical Center (AMC, Amsterdam),
Maquet

Intervention

Outcome measures

Primary outcome

The main study parameter is point accuracy of continuous glucose monitoring–measurements as compared to current arterial blood glucose measurements.

Secondary outcome

Other study parameters include trend accuracy and reliability of the system.

Study description

Background summary

Rationale: Insulin infusion in critically ill patients mandates frequent measurements of the blood glucose level. Several systems for continuous glucose monitoring have been developed, including systems that use microdialysis. Microdialysis is a well–established technology that offers the opportunity to sample blood analytes with high accuracy, but without drawing blood.

Objective: The primary objective of this study is to determine the point accuracy of a microdialysis–based continuous glucose monitoring system.
Secondary objectives include trend accuracy and reliability of the system.

Study design: This study concerns an investigator–initiated observational study in consecutive critically ill patients subjected to routine care–insulin infusion adjusted to reach blood glucose levels between 90 and 144 mg/dL (i.e., between 5 and 8 mmol/L).

Study population: Critically ill patients admitted to the Intensive Care Unit (ICU) of the Academic Medical Center at the University of Amsterdam, Amsterdam, The Netherlands.

Interventions (if applicable): Insertion of the microdialysis system (EIRUSTM) into a central vein through a specialized central venous catheter (i.e., the specialized central venous catheter replaces the normally–used intravenous catheter). In blocks of 8 hours per day for a maximum of 3 days, every 15 minutes a reference blood glucose measurement is performed on blood taken from an existing arterial catheter.

The microdialysis system: EIRUSTM is a continuous monitoring platform for glucose that has been adapted specifically for the needs of intensive care medicine. EIRUSTM offers continuous, second–by–second monitoring of the blood glucose level. Its multipurpose central venous catheter provides microdialysis monitoring, but also normal venous access.

Main study parameters/endpoints: The main study parameter is point accuracy of continuous glucose monitoring–measurements as compared to current arterial blood glucose measurements. Other study parameters include trend accuracy and reliability of the system.

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

The system has been tested and validated in a number of pre–clinical studies in non–ICU patients, and has been found to be safe and accurate in that setting. The device uses a special central venous catheter, which prevents the need for another central venous lines (i.e., the specialized central venous catheter replaces the normally–used intravenous catheter). Patients participating in this study are subjected to extra blood draws to a maximum of up to 12 ml over three days (i.e., a maximum of up to 4 ml per day), which is considered acceptable and safe. Patients could benefit from the study since continuous glucose monitoring could improve titration of insulin, in particular by preventing insulin–induced hypoglycemia.

Study objective

The primary objective of this study is to determine the point accuracy of a microdialysis–based continuous glucose monitoring system. Secondary objectives include trend accuracy and reliability of the system.

Study design

Patients will be monitored with the continuous glucose monitor for at most 72 hours. In blocks of 8 hours per day for a maximum of 3 days, every 15 minutes a reference blood glucose measurement is performed on blood taken from an existing arterial catheter.

Intervention

Insertion of the microdialysis system (EIRUSTM) into a central vein through a specialized central venous catheter (i.e., the specialized central venous catheter replaces the normally–used intravenous catheter). In blocks of 8 hours per day for a maximum of 3 days, every 15 minutes a reference blood glucose measurement is performed on blood taken from an existing arterial catheter.

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Eligibility criteria

Inclusion criteria

• At least 18 years old

• Arterial catheter needed for standard care present

• Central venous catheter needed for standard care

• Admitted to the ICU

• Expected to stay in the ICU for at least 48 hours

Exclusion criteria

• Currently participating in another investigational drug or device study; or

• Known pregnancy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-04-2014
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-04-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41459
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4396
NTR-old	NTR4527
CCMO	NL47628.018.14
OMON	NL-OMON41459

Study results