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

Gepubliceerd: 17-04-2014 Laatst bijgewerkt: 15-05-2024

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.

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

Samenvatting

ID

NL-OMON27403

Bron
NTR

Verkorte titel
ACSI

Aandoening

Blood glucose, Monitoring, Critically ill patients

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC, Amsterdam)
Overige ondersteuning: Academic Medical Center (AMC, Amsterdam), Maquet

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

• Known pregnancy.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-04-2014
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-04-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41459
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten