Manual vs. Automated moNitoring Accuracy of GlucosE.

Gepubliceerd: 18-04-2011 Laatst bijgewerkt: 13-12-2022

The OptiScanner provides accurate blood glucose levels in critically ill patients.

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

Samenvatting

ID

NL-OMON21703

Bron
NTR

Verkorte titel
MANAGE

Aandoening

blood glucose regulation
critically ill patients

Ondersteuning

Primaire sponsor: Academic Medical Center
Meibergdreef 9
1105 AZ Amsterdam
The Netherlands
OptiScan Biomedical Corporation
Hayward (CA)
United States of America
Overige ondersteuning: fonds = verrichter = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

13-aug-2012:
1. Glucose prediction error, defined as the results of the YSI versus the OptiScanner, using arterial blood;
2. Clarke Error Grid analysis showing the percentage of paired data values falling within each zone between the results of the YSI versus the OptiScanner, using arterial blood;
3. Linearity between the results of the YSI versus the OptiScanner, using arterial blood.

Toelichting onderzoek

Achtergrond van het onderzoek

13-aug-2012:
ntroduction:

Hyperglycemia, hypoglycemia, and glycemic variability are all associated with morbidity and mortality of critically ill patients. Blood glucose control with insulin prevents hyperglycemia but is associated with a higher incidence of hypoglycemia and may not decrease blood glucose variability. Implementation strategies of blood glucose control with insulin in critically ill patients have mainly used manually operated whole blood portable glucose meters, which suffer from a variety of error sources that can put these patients at risk for insulin over– and/or under–dosing. Continuous or near–continuous blood glucose monitoring devices have the potential to improve the safety (i.e., prevention of hypoglycemia) and effectiveness (i.e., obtain a higher percent of values in the therapeutic range and decrease blood glucose variability) of blood glucose control with insulin in critically ill patients. OptiScan Biomedical Corporation has developed a near–continuous glucose monitoring technology, called the OptiScanner, which provides accurate blood glucose measurements at a wide range of glucose concentrations.

Hypotheses:

The OptiScanner provides accurate blood glucose levels in critically ill patients.

Study design:

This is an investigator–initiated observational study comparing the OptiScanner with 3 standard blood glucose meters in critically ill patients subjected to glucose control with insulin.

Objectives:

The objective of this study is to demonstrate the accuracy of the OptiScanner in measuring blood glucose levels in critically ill patients when compared to a reference YSI 2300 STAT Plus (Yellow Springs Instruments) reading. The study will also compare readings taken from the OptiScanner to whole blood glucose measurements by the RAPIDlab 1265 (Siemens).

Study population:

Patients admitted to the intensive care units of the Academic Medical Center, Amsterdam or the Gelre Hospitals Apeldoorn, the Netherlands, with an expected length of stay ≥ 3 days.

Intervention:

The OptiScanner is a point of care device for measurement of blood glucose as well as other analytes. It works by measuring the optical infrared absorption of glucose in a very small amount of plasma. Blood is drawn into the measurement engine of the device, a mid–infrared spectrometer, on a near–continuous basis.

Main study parameters/endpoints:

1. Glucose prediction error, defined as the results of the YSI versus the OptiScanner, using arterial blood;

2. Clarke Error Grid analysis showing the percentage of paired data values falling within each zone between the results of the YSI versus the OptiScanner, using arterial blood;

3. Linearity between the results of the YSI versus the OptiScanner, using arterial blood.

Secondary study parameters/endpoints:

1. Glucose prediction error, defined as the results of the OptiScanner, versus the RAPIDlab, using arterial blood;

2. Clarke Error Grid analysis showing the percentage of paired data values falling within each zone between the results of the OptiScanner versus the RAPIDlab, using arterial blood;

3. Linearity between the results of the OptiScanner versus the RAPIDlab, using arterial blood.

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

The OptiScanner has been tested and validated in a number of pre–clinical and clinical studies, and has been found to be both safe and accurate. Potential benefits include reduced risk of hypoglycemia, and decreased glycemic variability.

Doel van het onderzoek

The OptiScanner provides accurate blood glucose levels in critically ill patients.

Onderzoeksopzet

13-aug-2012:
Every day (for a maximum of 3 days), 12 blood samples (total of 36) will be drawn to be compared to the OptiScanner measurements.

Onderzoeksproduct en/of interventie

13-aug-2012:
The OptiScanner is a point of care device for measurement of blood glucose as well as other analytes. It works by measuring the optical infrared absorption of glucose in a very small amount of plasma. Blood is drawn into the measurement engine of the device, a mid–infrared spectrometer, on a near–continuous basis.

Next to this, 12 blood samples per day will be drawn to be compared with measurements with a ysi 2300 stat plus, and RAPIDlab blood gas analyser.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Signed Informed consent;

2. Age ≥ 18 years;

3. Admitted to the ICU of the Academic Medical Center or Gelre Hospitals Apeldoorn;

4. Expected ICU stay of ≥ 3 days at the time of enrollment (as judged by Principle Investigators);

5. APACHE II score of ≥ 10, within the first 24 hours of ICU admission;

6. Existing central venous catheter + arterial catheter;

7. No participation in any other investigational interventional study while enrolled in this study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Have received any investigational product or been treated with an investigational device within the past 30 days;

2. Pregnancy;

3. Untreatable colonization with multi–resistant bacteria (e.g. methicillin–resistant Staphylococcus aureus).

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 nog niet gestart
(Verwachte) startdatum:	20-09-2011
Aantal proefpersonen:	75
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	18-04-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2726
NTR-old	NTR2864
Ander register	METC AMC : 10/281 # 10.17.1900

Register	ID
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A