Manual vs. Automated moNitoring Accuracy of GlucosE.

No registrations found.

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

Summary

ID

NL-OMON21703

Source
NTR

Brief title
MANAGE

Health condition

blood glucose regulation
critically ill patients

Sponsors and support

Primary sponsor: Academic Medical Center
Meibergdreef 9
1105 AZ Amsterdam
The Netherlands
OptiScan Biomedical Corporation
Hayward (CA)
United States of America
Source(s) of monetary or material Support: fonds = verrichter = sponsor

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

13-aug-2012:
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.

Study description

Background summary

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.

Study objective

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

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

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:	Pending
Start date (anticipated):	20-09-2011
Enrollment:	75
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-04-2011
Application type:	First submission

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
NTR-new	NL2726
NTR-old	NTR2864
Other	METC AMC : 10/281 # 10.17.1900
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A