Manual vs. Automated moNitoring Accuracy of GlucosE (MANAGE)

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The objective of this study is to demonstrate the accuracy of the OptiScanner in measuring blood glucose levels in critically ill patients.

Ethical review	-
Status	Pending
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON34611

Source
ToetsingOnline

Brief title
MANAGE

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Critical illness associated hyperglycemia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Optiscan, Hayward, USA,Optiscan;Hayward;USA

Intervention

Keyword: blood glucose, intensive care, monitoring

Outcome measures

Primary outcome

* Glucose prediction error, defined as [the YSI (the "gold standard") versus the OptiScanner result, as well as all other measurement technologies used on central venous blood].

* Clarke Error Grid analysis between the YSI and the OptiScanner result, to show the percentage of paired data values falling within each zone.

* Linearity between the YSI and the OptiScanner, as well as all other measurement technologies used on central venous blood.

Secondary outcome

* Glucose prediction error, defined as [the YSI versus all other measurement technologies used on arterial blood].

* Clarke error grid analysis between the YSI and all other measurement technologies used on arterial blood.

* Linearity between the YSI and all other measurement technologies used on arterial blood.

Study description

Background summary

Critically ill patients frequently have hyperglycemia. Blood glucose control with insulin prevents hyperglycemia but is associated with a higher incidence of hypoglycemia and may even increase blood glucose variability. Both are associated with adverse effects.

Blood glucose control with insulin utilizing manual systems for glucose measurement is blood*consuming, since frequent blood draws for glucose measurements are necessary in order to achieve adequate blood glucose control. OptiScan Biomedical Corporation has developed a glucose monitoring technology, called the OptiScanner, that measures the infrared absorption of glucose in a very small sample of heparinized plasma, created from approximately 120 uL of a patient*s blood.
The OptiScanner has been safe in healthy volunteers and patients outside the Intensive Care unit.

Study objective

The objective of this study is to demonstrate the accuracy of the OptiScanner in measuring blood glucose levels in critically ill patients.

Study design

Every 15 minutes the OptiScanner collects a little amount of blood - every 4 hours an extra blood sample will be collected from the same central catheter for comparison. Results of these measurements will not be used to titrate insulin.

Study burden and risks

It is standard practice to collect blood from an indwelling arterial line for blood glucose measurement once every 4 hours - this will not be changed in this study and remains the way to monitor blood glucose levels and titrate insulin. The test patient will not be aware of the measurements: the Optiscanner is connected to an existing central venous line; there is no need for extra catheters, and blood will not be collected via extra venapunctures.
In total, 22 mL blood will be collected per day - this amount is negligible. In addition, on 3 successive days an extra blood sample of 4 mL will be collected - this amount is also negligible.
The total amount of saline that is used to return back the remainder of the blood sample + the amount of saline to keep the line open is less than 350 mL per day, which is also considered clinically insignificant.

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

* Informed consent.
* Age > 18 years.
* Admitted to the ICU of the Academic Medical Center.
* Expected ICU stay of * 3 days at the time of enrolment (as judged by Principle Investigator).
* APACHE II score of * 10.
* Existing central venous catheter + arterial catheter.
* No participating in any other investigational interventional study while enrolled in this study.

Exclusion criteria

* Have received any investigational product or been treated with an investigational device within the past 30 days.
* Pregnancy.
* Untreatable colonization with multi*resistant bacteria (e.g., methicillin*resistant Staphylococcus aureus).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2010
Enrollment:	75
Type:	Anticipated

Medical products/devices used

Generic name:	Optiscanner
Registration:	Yes - CE intended use

Ethics review

Not available

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	NL34465.018.10
Other	volgt