Randomised study to the efficacy and safety of Continuous Glucose Monitoring by subcutaneous measurement compared to frequent point of care measurement by Accu-Chek in critically ill patients (RESCUE)

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To compare the efficiency and safety of Continuous subcutaneous glucose monitoring compared to our standard care (bloodsamples obtained from an arterial or venous bloodsample and measured by the AccuChek.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON34710

Source
ToetsingOnline

Brief title
RESCUE

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes mellitus, sugar disease

Research involving

Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: stichting invensief (ICU)

Intervention

Keyword: blood glucose, critical illness, hypoglycemia, intensive care

Outcome measures

Primary outcome

- Number of hypoglycemia or low glucose levels per 24 hour period

- Amount of time in which the patient blood glucose levels are in the blood

glucose target range.

Definitions:

- Hypoglycemia: glucose level< 2,5 mmol/l

- Low glucose level: glucose level < 2,5-5,0 mmol/l

- Hyperglycemia: glucose level > 9 mol/l

- Severe hyperglycemia: glucss > 25 mmol/l

Secondary outcome

- Amount of time in which the patient blood glucose levels are above or beneath

the blood glucose target range.

- Variability of the glucose regulation measured with the blood gas analyser.

(use of arterial bloodsamples) Expressed as mean Absolute Glucose

change per hour (MAG).

- Length of stay on the ICU

- Mortality

- False positive alarms of the Freestyle Navigator

- Number of not detected hypoglycemia by the AccuChek.

- Number of obtained bloodsamples per day per patient

Study description

Background summary

The Van den Berghe-studies in 2001 and 2006 showed an improved outcome for critically ill patients with strict glucose regulation. However, in a recent meta-analysis, benefit of strict glucose regulation was not found. Moreover, strict glycaemic control increases the risk of hypoglycaemia (NICE-SUGAR trial). Another study found that intensive glucose control increased mortality among adults in the Intensive Care Unit. This could be caused by hypoglycaemia. These days it is common to use a higher blood glucose target in critically ill adults.
The ICU of the Onze Lieve Vrouwe Gasthuis implemented a computerized guideline for glucose regulation of critically ill patients. The guideline recommends the timing between glucose measurements and the administration of insulin doses. The recommended interval varies between 15 minutes and six hours, depending on stability of arterial blood glucose concentration. Arterial blood samples are analyzed by AccuChek . The AccuChek uses the enzyme glucose dehydrogenase and an amperometric end-point to measure glucose. The AccuChek-Inform has been tested in critically ill patients before. A mean number of 10 bloodsamples are taken per patient per day.

Continuous Glucose Monitoring Systems (CGMS) may have the potential for strict regulation without the dangers of hypoglycemia. The continuous feedback may lead to the prevention of variation and swings in glucose levels and may reduce the risk of hypoglycaemia compared to an interval point-of-care glucose meter. Moreover, the use of CGMS may decrease workload for the nurses, since less glucose measurements have to be performed. In addition, CGMS will reduce the frequency and quantity of blood loss, because the only need for a blood sample is to calibrate the system. Other advantages may be:
- cost reduction
- better knowledge of glucose levels in critically ill patients
- early detection of hypglycemia

Study objective

To compare the efficiency and safety of Continuous subcutaneous glucose monitoring compared to our standard care (bloodsamples obtained from an arterial or venous bloodsample and measured by the AccuChek.

Study design

Randomised open label study.

Study burden and risks

The risk for paticipants is judged to be minor. The insertion and wearing of the sensors is minimally invasive. The Freestyle Navigator is a miniature electrochemical sensor placed in the subcutaneous adipose tissue.

In total a maximum of 20 arterial or venous bloodsamles of 1.5 ml will be obtained besides standard care samples. The bloodsamples will be obtained from an intra arterial or intravenous catheter. Insertion of these catheters are standard care on the ICU.The arterial line is routinely in situ for routine blood sampling and continuous monitoring of blood pressure.

Continiuous glucose montinoring on the ICU has several advantages compared to point-of-care glucose measurement. The first is early detection of hypoglycaemia. The Freestyle Navigatior CGM system is equipped with an alarm function to indicate hyper- and hypoglycemia.

The second advantage is a limitation of blood loss by sampling. In patients receiving intensive insulin therapy, frequent determination of blood glucose is needed. The point-of-care measurement needs blood to be drawn for every glucose determination. (1.5 ml). Continuous glucosemonitoring with the Freestyle Navigator does not require additional bloodsamples, only when the glucose level is under or above the target range, or to calibrate the system. (which is at a maximum of twice daily)

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

-ICU patients of 18 years and older
-Expected length of stay longer than 24 hours
-Indication for glucose regulation with insuline. (see appendix study protocol)

Exclusion criteria

- Participation in another WMO study
- No informed consent
- Contra indication for the use of the AccuChek: (peritoneal dialysis, Hematocrit< 0,20 or > 0,65 , paracetamol intoxication)
- Abdominal abnormalities that inhibit sensor insertion
- Participation of the same study in an earlier ICU admittance.

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-03-2010
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	15-03-2010
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL31006.099.09