Continuous Glucose Monitoring by subcutaneous measurement compared to frequent point of care measurement by Accu Chek in critically ill patients; a randomized controlled trial (RESCUEII).

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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	Interventional

Summary

ID

NL-OMON34507

Source
ToetsingOnline

Brief title
RESCUE II

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: Ministerie van OC&W

Intervention

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

Outcome measures

Primary outcome

- Number of severe hypoglycemia and severe hyperglycemia

Definitions:

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

- Severe hyperglycemia: glucss > 25 mmol/l

Secondary outcome

- Amount of time in which the patient blood glucose levels are in the blood glucose target range (measured with the Freestyle Navigator)

- Amount of time in which the patient blood glucose levels are above or beneath the blood glucose target range. (measured with the Freestyle Navigator)

- 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 unwanted low glucose every 24 hours (glucose between 2.5 - 5.0

mmol)

- Number of not detected hypoglycemia by the AccuChek. (measured with the

Freestyle Navigator)

- Number of obtained bloodsamples per day per patient

Study description

Background summary

Strict glucose regulation is part of the standard IC treatement since the Van den Berghe-studies in 2001 and 2006 showed an improved outcome for critically ill patients with strict glucose regulation (blood glucose between 4 and 6 mmol/l) . However, in other multicenter trials and 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.

Strict glucose regulation is performed at the ICU of the OLVG. Therefore we implemented a computerized guideline for glucose regulation of critically ill patients. We measure glucose levels with frequent arterial blood samples which are analyzed by point of care measurement (AccuChek.)

Nowadays a continuous subcutaneous glucose monitoring (CGM),which is also applicable and reliable for crititically ill patients, is available.

Advantages if continuous glucoes measuremnt in IC patients may be:
- cost reduction
- better knowledge of glucose levels in critically ill patients
- early detection of hypglycemia
- less blood samples required
- less tasks for the IC nurses

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

Critically ill patients admitted on the intensive care unit of the Onze Lieve Vrouwengasthuis with a minimum age of 18 years. Patients which are applicable to the activation of our ICU glucose protocol (see appendix 2 of the studyprotocol pg 14) and gave informed consent will be included in our study.

Intervention

The continuous glucose measurement (CGM) device (Freestyle navigator) will be inserted in both study groups. We will only use the results of the intervention group. The results of the control group will be blinded.

The FreeStyle Navigator® CGM system (Abbott Diabetes Care, Alameda, CA) is a miniature electrochemical sensor placed in the subcutaneous adipose tissue and transmits data through radiofrequency to receiver, which also displays continuous glucose values. Glucose is measured in the interstitial fluid . The size of the freestyle Navigator is a few cm2.
Calibration is required 5 times during the study: after 1 hour, 2 hours, 8 a 10 hours, 24 a 32 hours and 72 a 80 hours.

The Freestyle Navigator will start to measure after the first callibration.
Before this time the Accu Chek will be used.

Every four hours, glucose in both groups is measured with an arterial blood gas analyzer. (ABL800 flex, Radiometer Copenhagen)

Intervention group: The glucose level measured with the Freestyle Navigator wil be inserted in the computerized protocol for glucose regulation .
Control group: The glucose level measured with the standard method (Accu Chek) will be inserted in the computerized protocol for glucose regulation.

The sensor lasts a maximum of 5 days. After these 5 days the study will be finished. The subcutaneous sensor will be removed.

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. The sensor is about 2 cm2. The sensor will be attached to the skin with a plaster.
The sensor will last for a maximum of 5 days.The Freestyle will stop measuring after 5 days. This will be the end of the study. The subcutaneous sensor will be removed.

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.

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)
- Availability of the Freestyle Nagivator

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:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-12-2010
Enrollment:	178
Type:	Actual

Medical products/devices used

Generic name:	Continuous glucose monitoring system
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	25-11-2010

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL33495.100.10