Artificial Pancreas Research at the Intensive Care: AMC OLVG Trial

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To investigate the feasibility and efficacy, expressed as percentage funcitoning time and time in target range, respectively, of an automated closed-loop glucose control system based on subcutaneous continuous glucose measurements in critically ill...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON40647

Source
ToetsingOnline

Brief title
APRICOT

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes mellitus, stress-hyperglycaemia

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: Ministerie van OC&W,Abbott Inc. ,Apparatuur (sensoren + communicatieapparatuur) wordt gratis verstrekt door Abbott.

Intervention

Keyword: closed-loop, continuous glucose monitor, glucose, intensive care

Outcome measures

Primary outcome

The primary endpoint will be the time spent in target glucose range (6-9 mmol/l) as recorded by reference glucose measurements.

Secondary outcome

Other study parameters include time spent in glucose levels above and below target range, mean reference glucose, sensor accuracy metrics, insulin infusion rates, and nursing workload. Safety measures include frequency of hypoglycaemic (< 3.0 mmol/l) and hyperglycaemic (>15 mmol/l) events and other adverse events.

Study description

Background summary

Glucose regulation has become a key patient management goal in intensive care medicine. Closed-loop glucose control modulates insulin delivery according to glucose levels with use of continuous glucose measurements without nurse input.

Study objective

To investigate the feasibility and efficacy, expressed as percentage funcitoning time and time in target range, respectively, of an automated closed-loop glucose control system based on subcutaneous continuous glucose measurements in critically ill adults.

Study design

single centre, open-label, randomised controlled study

Intervention

Subjects will be randomized to either closed-loop insulin delivery (intravenous infusion delivery of insulin and glucose (dextrose), dose calculated by glucose control algorithm, based on continuous glucose sensor readings) or open-loop insulin delivery (standard treatment) (standard intravenous insulin infusion using a sliding scale glucose algorithm as per intensive care unit protocol). All patients receive a Freestyle Navigator subcutaneous glucose sensor. The Freestyle Navigator sensor will be blinded in the open-loop group.

Study burden and risks

The Freestyle Navigator CGM System has been used in a number of other clinical trials with no adverse events. The potential risks related to placement of the sensor placement include bleeding > 1mL (uncommon), swelling or redness (infrequent), bruising > 1cm (infrequent) and infection (rare). Extra blood sampling indicates that approximately 1.5 mL of blood per sample will be discarded, for a maximum of 22.5 mL (15 x 1.5mL) blood loss during the study. It is expected that this protocol will yield increased knowledge about the feasibility and efficacy of a closed loop glucose control system with use of Freestyle Navigator CGM reported glucose levels. The scientific knowledge which could be gained from this research is a fair balance to aforementioned minimal risks.

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

Age >= 18 years
• Diabetic and non-diabetic patients with an anticipated stay of at least 24 hours of admission to the intensive care
• Indication for glucose regulation with insulin (according to the current glucose treatment protocol)
• Patient or surrogate understands and signs informed consent document.

Exclusion criteria

• Patients with diabetic ketoacidosis or hyperosmolar hyperglycaemic non-ketotic coma
• Patients who are receiving therapeutic hypothermia
• Pregnancy
• Any disease or condition which the investigator or treating physician feels would interfere with the trial or the safety of the patient

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:	Will not start
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Generic name:	Freestyle Navigator II continuous glucose monitoring system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-06-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-02-2016
Application type:	Amendment
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
ClinicalTrials.gov	NCT
CCMO	NL50562.100.14