Glucerna in Critically ill Patients (GluCip trial): Investigating the glycaemic effects of a reduced-carbohydrate, modified-fat, fiber-containing enteral formula (Glucerna®) in critically ill patients.

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To investigate whether the administration of Glucerna achieves less glycaemic variability, defined as the mean absolute glucose (MAG) change, and greater glycaemic control compared to a standard high-carbohydrate enteral formula. Continuous glucose...

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

Summary

ID

NL-OMON42200

Source
ToetsingOnline

Brief title
GluCip Trial

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, glucose variability, stress-hyperglycaemia

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: Abbott Inc. ,gedeeltelijke sponsoring van sensoren door Abbott Inc;overig via externe financiering van onderzoeksstichting van de intensive care.

Intervention

Keyword: blood glucose regulation, continuous glucose monitoring, Enteral feeding, glucose variability

Outcome measures

Primary outcome

The primary outcome will be the extent of glucose variability, defined as the

mean absolute glucose (MAG) change (delta glucose/delta time) in mmol/l/hr,

measured by continuous glucose monitoring technology.

Secondary outcome

Secondary outcomes include: time in target range (between 6-9 mmol/l) and below

and above target range, mean (sensor) glucose, standard deviation of glucose

values, severe hypo- and hyperglycaemic events (<2.2 mmol/l and > 15.0 mmol/l),

amount of insulin use, daily nutritional administration, clinical

gastrointestinal symptoms.

Study description

Background summary

Glucerna® is a reduced-carbohydrate, modified-fat, fiber-containing enteral formula, which is designed to improve glucose control in patients prone to hyperglycaemia. The potential role for Glucerna as a non-insulin alternative to better control glucose levels in critically ill patients has not been established yet.

Study objective

To investigate whether the administration of Glucerna achieves less glycaemic variability, defined as the mean absolute glucose (MAG) change, and greater glycaemic control compared to a standard high-carbohydrate enteral formula. Continuous glucose monitoring technology will be used to evaluate glycaemic variability and glycaemic control.

Study design

Single centre, open-label randomised controlled study

Intervention

Subjects will be randomized to either Glucerna® 1.5 kcal (Abbott, USA), the standard enteral formula used at our ICU and the investigational enteral feeding, or Fresubin® Energy Fibre (Fresenius, UK), the control enteral feeding. All subjects will receive a Freestyle Navigator subcutaneous continuous glucose monitoring (CGM) system to record the glycaemic status of the subject.

Study burden and risks

No risks related to the type of enteral feeding are expected. Both types of enteral feeding are now used (Glucerna) or have been used (Fresubin) as the standard enteral feeding in our ICU for a considerable amount of time. The Freestyle Navigator CGM system has already been used in a number of other clinical trials without any adverse events. Risk related to the placement of the Freestyle Navigator CGM system include bleeding > 1ml (uncommon), swelling or redness (infrequent) bruising > 1cm (infrequent) or infection (rare). The Freestyle Navigator will be calibrated during the study at five set time points, which requires 0,5mL blood drawn from an existing arterial line (in total 5x0,5mL = 2,5mL during the study). It is expected that this protocol will yield increased knowledge about the glycaemic effects of a disease-specific enteral feeding. The scientific knowledge which could be gained from this research is in 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
Patients with an anticipated stay of at least 24 hours of admission to the intensive care
Expected to receive enteral feeding for at least 72 hours
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 pre-existing contraindications to enteral feeding or to placement of a CGM system
Patients previously randomised into the GluCip trial
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:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2015
Enrollment:	90
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	14-04-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-08-2015
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
CCMO	NL51918.100.14