Real Time Continuous Glucose Monitoring in Neonatal Intensive Care

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Purpose of the clinical study: To evaluate the effectiveness, safety and usability of real time continuous glucose monitoring (rCGM) in neonatal intensive care (NICU)Primary objective:* To evaluate the effectiveness of rCGM in the regulation of...

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

Summary

ID

NL-OMON47310

Source
ToetsingOnline

Brief title
REACT study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
hypo- and hyperglycaemia in premature children

Research involving
Human

Sponsors and support

Primary sponsor: Cambridge University Hospitals NHS Foundation Trust and University of Cambridge
Source(s) of monetary or material Support: University of Cambridge

Intervention

Keyword: Glucose, premature

Outcome measures

Primary outcome

Time percentage of sensor glucose (SG) within the target of 2.6-10 mmol/L

within the first six days of life of premature children

Secondary outcome

Efficacy

1) Mean sensor glucose (SG) in the first six days.

2) Time percentage of SG within the target of 4-8 mmol/L within the first six

days of life

3) SG variability in individuals as established by standard deviation in the

patient

4) Time percentage of glucose levels in hyperglycaemic region - SG > 15 mmol/L

Acceptability

1) Assessment score of the clinical staff on the impact on clinical care

2) Frequency of blood glucose monitoring

3) Clinical use of algorithm

Safety

1) Incidence of hypoglycaemia defined as an episode of blood glucose

>2.2 mmol/L and <2.6 mmol/L

2) Incidence of hypoglycaemia defined as a continuous episode of SG < 2.6

mmol/L for > 1 hour

3) Incidence of severe hypoglycaemia defined as an episode of BG *2.2 mmol/L

Economic aspects for health care

*

Cost efficiency expressed in terms of increasing costs per additional

case of adequate glucose control between 2.6 mmol/L - 10 mmol/L

Study description

Background summary

Increasing numbers of infants are being born preterm. These infants require intensive care and have a high risk of early mortality and short term morbidity. Surviving infants have a high incidence of long term health problems, including learning difficulties with significant long term costs to the NHS and society. Treatable neonatal causes of long term health problems have been difficult to establish. National proirities for Research have highlighted investigation of the management of babies born too early or too small, and evaluation of the reasons for variations in outcome of "high risk" neonates.
Early postnatal glucose control may be aan important modifiable risk factor for clinical outcomes. In utero, glucose levels are normally maintained between 4-6 mmol/L, but infants born premature are at risk of both hyperlgycaemia (20-86%,

depending on how it is defined) and hypoglycaemia (<2.6 mmol/l, 17%).

Study objective

Purpose of the clinical study: To evaluate the effectiveness, safety and usability of real time continuous glucose monitoring (rCGM) in neonatal intensive care (NICU)

Primary objective:
* To evaluate the effectiveness of rCGM in the regulation of glucose levels in premature children
* To evaluate the clinical acceptability in premature children
* To evaluate the safety in terms of risk of hypoglycaemia in premature children

Secondary objective:
* To evaluate the cost efficiency and the importance of such an intervention for the national health service

Study design

Purpose of the clinical study:
To evaluate the effectiveness, safety and usability of real time continuous glucose monitoring (rCGM) in neonatal intensive care (NICU)

Study design: Multicentre randomised controlled study

Baseline:
* Inclusion/exclusion
* Randomisation
* Demographics
* Clinical condition

Intervention period:

Cases

Day 1 * Day 6:
* Insertion of the glucose sensor
* Collection of glucose data by continuous real time glucose monitoring
* Glucose monitoring based on amended paper algorithm
* Further clinical particulars are recorded
* Day 3 - Clinical questionnaire

Controls:

Day 1 * Day 6:
* Insertion of the glucose sensor
* Collection of glucose data by continuous glucose monitoring not visible to the medical team
* Glucose monitoring according to standard clinical practices
* Further clinical particulars are recorded

Follow-up period after the intervention: Day 7 to 36 weeks gestational age

Day 7:
Removal of the glucose sensor
Clinical questionnaire
Cases have a parent questionnaire

Day 14:
Checking the sensor site
Clinical particulars are recorded
Length, weight, head circumference

End of the study: 36 weeks corrected gestational age Clinical condition

Length, weight, head circumference Assessment of the use of means
Level of care (BAPM classification)

Study burden and risks

The baby may experience some discomfort when the sensor is inserted and there is a small risk of mild bruising at the sensor site. The sensor does not cause any discomfort once it has been inserted. There is a risk of infection, but this has not occurred in the 400 cases in the privious studies. Similar sensors have been used in more than 400 premature babies without any complications.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

* Informed consent of the parents
* * 33+6 weeks gestation
* * 24 hours of age
* Birth weight * 1200 g

Exclusion criteria

* A fatal congenital defect known at the time of enrolment in the study.
* All congenital metabolic disorders known at the time of enrolment in the study.
* Newborns who in the opinion of the treating doctor have no realistic prospect of survival at the time of enrolment in the study

Study design

Design

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

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-07-2017
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Enlite sensor en Minimed 640 G system
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	30-01-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-12-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
Other	12793535
CCMO	NL58499.029.16