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Can a glucose sensor improve control of sugar levels of premature babies in intensive care?

Submission date
14/05/2015

Recruitment status
No longer recruiting

Registration date
15/05/2015

Overall study status
Completed

Last Edited
15/02/2021

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Both high and low blood sugar (glucose) levels are common in preterm babies and this has been linked with poor outcome. Managing these sugar levels in preterm babies is difficult as individual babies respond very differently to treatment and checking sugar levels currently involves taking blood samples. Clinical teams try to avoid taking blood samples and there can therefore be a relatively long time between taking measurements. In contrast other parameters like blood pressure and levels of oxygen are measured continuously. There is now a device 'real time continuous glucose monitoring' (rCGM) that is used by some children and adults with diabetes which can provide continuous data on sugar levels. This involves a small sensor being placed under the skin, but it can be left there for up to a week and allows the medical team to respond quickly and treat changes in sugar levels to keep the sugar level within a normal range. Our previous study investigated how easy it was to use rCGM in a neonatal intensive care setting and the impact it had on the number of blood tests babies have. We are now expanding upon this, developing and running a study to compare rCGM with standard care. The aim is to determine if rCGM with a new paper-based algorithm can help improve glucose control, is clinically acceptable, and is safe in these preterm infants.

Who can participate?
Pre-term babies within 24 hours of birth and with a birth weight of 1200 g or lower.

What does the study involve?
Participating babies are randomly allocated to either have rCGM with a paper-based algorithm to guide sugar control, or standard care with glucose monitored but with data hidden from the clinical team. The intervention is for the first week of their life. The percentage of time that blood glucose is in the target range is measured.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Addenbrooke's Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2012 to July 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Kathryn Beardsall
kb274@medschl.cam.ac.uk

Study website
http://paediatrics.medschl.cam.ac.uk/research/clinical-trials/real-time-continuous-glucose-monitoring-newborn-react/

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number
168042

ClinicalTrials.gov number

Secondary identifying numbers
CRN 18826, IRAS 168042

Study information

Scientific Title
Real time continuous glucose monitoring in neonatal intensive care: a randomised controlled trial

Acronym
REACT RCT

Study objectives
The aim of this study is to determine if 'real time continuous glucose monitoring' (rCGM) with a new paper based algorithm can help improve glucose control and is clinically acceptable and safe for preterm infants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East of England - Cambridge Central, 28/07/2015, 15/EE/0158

Study design
Randomised; Interventional; Design type: Diagnosis

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Topic: Children; Subtopic: All Diagnoses; Disease: All Diseases

Interventions
Updated interventions as of 21/09/2018:
Eligible babies are randomised within 24 hours of age through TENALEA (web based randomisation program) using a 1:1 ratio to either the treatment arm or the control arm.

Intervention Arm: Real-time continuous glucose monitoring (rCGM) with paper-based algorithm. A glucose sensor is inserted to transmit data to real-time continuous glucose monitor to support clinical management for up to 6 days. The sensor is removed on day 7.

Control Arm: Standard clinical management with continuous glucose monitoring data blinded to the clinical team. A glucose sensor is inserted to collect blinded data using continuous glucose sensor for up to 6 days. The sensor is removed on day 7.

Follow up for both arms:
Day 14
Sensor site checked
Clinical details recorded including length, weight and head circumference

At 36 weeks corrected gestation
Assessment of resource used and clinical details recorded including length, weight and head circumference.

Previous interventions:
Insertion and removal of sensor (replacements may be necessary)
Study Entry : Registration and one or more randomisations

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Percentage of time sensor glucose in target of 2.6-10mmol/l within the first 6 days of life in preterm infants

Secondary outcome measures
1. Efficacy
2. Acceptability
3. Safety
4. Health economics

Overall study start date
01/01/2012

Completion date
31/07/2019

Eligibility

Key inclusion criteria
1. Parental consent
2. Less than or equal to 1200g birth weight
3. Less than or equal to 24 hours of age
4. Less than or equal to 33+6 weeks gestation
5. Male & Female
6. Upper Age Limit 1 days; Lower Age Limit 1 days

Participant type(s)

Patient

Age group
Neonate

Sex
Both

Target number of participants
Planned Sample Size: 200

Total final enrolment
182

Key exclusion criteria
1. A lethal congenital abnormality known at trial entry
2. Any congenital metabolic disorder known at trial entry
3. Neonates who, in the opinion of the treating clinician at trial entry, have no realistic prospect of survival

Date of first enrolment
04/07/2016

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
England

Netherlands

Spain

United Kingdom

Study participating centre
Addenbrooke's Hospital (co-coordinating centre)
University Department of Paediatrics
University of Cambridge
Box 116
Cambridge Biomedical Campus
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

Sponsor details
Addenbrooke’s Hospital
Box 277
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ

Sponsor type
Hospital/treatment centre

Website
www.cuh.org.uk

ROR
https://ror.org/04v54gj93

Organisation
University of Cambridge (UK)

Sponsor details
Research Operations Office
Research Services Division
University of Cambridge
16 Mill Lane
Cambridge
England
United Kingdom
CB2 1SB

Sponsor type
University/education

Website
www.admin.cam.ac.uk/offices/research/

Funder(s)

Funder type

Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Further publications are planned to be submitted to a high-impact peer-reviewed journal one year after trial ending.

Intention to publish date
31/07/2020

Individual participant data (IPD) sharing plan
Data applications need to be made to Dr Kathryn Beardsall, Chief Investigator (kb274@medschl.cam.ac.uk). The type of data available is anonymised CRF data and continuous glucose monitoring (CGM) data. The data will become available after the publication of the primary results and will be available for 25 years.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/06/2018		Yes	No
Results article	results	01/04/2021	15/02/2021	Yes	No
HRA research summary			28/06/2023	No	No