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Control of hyperglycaemia in paediatric intensive care

Submission date	Recruitment status	[X] Prospectively registered
23/01/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/01/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/06/2016	Signs and Symptoms	

Plain English summary of protocol

Background and study aims
When children are severely ill or recovering from major surgery they often require treatment in specialist children's intensive care units. It is frequently observed that under such circumstances children's blood sugar levels rise. Traditionally this has been dismissed as unimportant. Recently research in the laboratory and adults has questioned this view. A large study randomly assigned adults in intensive care to conventional treatment (allowing blood sugar to rise) or to receive a drug, insulin, which was used to maintain blood sugar levels strictly within normal limits. There were 43% fewer deaths and similar reductions in serious complications in the adults receiving the insulin treatment. Babies and children are not small adults, and it cannot be assumed that the benefits seen in adults will occur in children. As we do not know whether the new blood sugar management will help children, the aim of this study is to compare conventional versus strict control of blood sugar in babies and children undergoing intensive care.

Who can participate?
Children from birth to 16 years of age who are undergoing intensive care treatment.

What does the study involve?
Participants are randomly allocated to receive either conventional care or the new strict blood sugar control treatment (insulin). We hope to find out whether strict control of blood sugar by using insulin leads to fewer deaths, fewer complications and faster recovery of children in intensive care.

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

Where is the study run from?
Royal Brompton Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2007 to April 2011

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
Dr Duncan Macrae
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Study website
http://www.chip-trial.org.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 05/506/03; 2006PC008B

Study information

Scientific Title
Control of Hyperglycaemia In Paediatric intensive care

Acronym
CHIP

Study objectives
Main hypothesis:
For children aged from birth to 16 years on ventilatory support, tight glucose control (TGC) will increase the numbers of days alive and free of mechanical ventilation at 30 days.

Secondary hypotheses:
That TGC will lead to improvement in a range of non-fatal complications associated with intensive care treatment and be cost effective.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/0550603
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0018/51228/PRO-05-506-03.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Brighton East REC, 01/06/2007, ref: 07/Q1907/24

Study design
Randomised controlled interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://chip.lshtm.ac.uk/information.html

Health condition(s) or problem(s) studied
Hyperglycaemia

Interventions
Group 1 - Standard treatment
Children in this group will be treated according to a standard, current, approach to blood glucose (BG) management. Insulin will be given by intravenous infusion in this group only if BG levels exceed 12mmol/l on two blood samples taken at least 30 minutes apart and will be discontinued once BG falls to =< 10 mmol/l.

Group 2 - Tight Glycaemic Control
Children in this group will receive insulin by intravenous infusion titrated to maintain a BG between the limits of 4 and 7.0 mmol/l.

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Insulin

Primary outcome measure
The number of days alive and free from mechanical ventilation within the 30 days after trial entry. Death is obviously an important outcome. Mechanical ventilation can be seen as a measure of disease severity, defining the need for complex intensive care. The concept of ventilator free days (Vedas) brings together these two outcomes. Schoenfeld et al define ventilator free days (VFDs) as: VFD=0 if the child dies before 30 days; VDF=(30-x) if the child is successfully weaned from ventilator within 30 days (where x is the no. of days on ventilator); or VFD=0 if the child is ventilated for 30 days or more. The use of organ failure free days to determine patient-related morbidity surrogate end-points in paediatric trials has been supported by influential paediatric trialists in the current low mortality paediatric critical care environment.

Secondary outcome measures
1. Death within 30 days after trial entry (or before discharge from hospital if duration is greater than 30 days)
2. Death within 12 months of trial entry
3. Number of days in ICU
4. Duration of mechanical ventilation
5. Duration of vasoactive drug usage (adrenaline, noradrenaline, dopamine, dobutamine, or phosphodiesterase type III [PDE-III] inhibitors or vasopressors)
6. Need for renal replacement therapy
7. Blood stream infection (positive cultures associated with two or more features of systemic inflammation or any positive blood culture for fungus)
8. Use of antibiotics >10 days
9. Number of red cell transfusions
10. Number of hypoglycaemic episodes moderate (less than 2.5 mmol/L), severe (less than 2.0 mmol/L)
11. Occurrence of seizures (clinical seizures requiring anticonvulsant therapy)
12. Organ dysfunction score (Pediatric Logistic Organ Dysfunction [PELOD])
13. Hospital length of stay
14. Number of children readmitted within 30 days of trial entry
15. Cost and cost-effectiveness measures:
15.1. Hospital costs within 30 days of trial entry
15.2. Cost per life year (based on 30 days costs and survival)
15.3. Hospital and community health service costs within 12 months of trial entry
15.4. Cost per life year (based on 12 month costs and survival for all cases)
15.5. Cost per disability-free survivor (based on 12 month cost and outcome data for sub group with brain injury)

Overall study start date
01/02/2007

Completion date
30/04/2011

Eligibility

Key inclusion criteria
Children from birth to 16 years who are undergoing intensive care treatment with an arterial line in-situ and receiving both mechanical ventilation and vasoactive support drugs following injury, major surgery or in association with critical illness in whom it is anticipated such treatment will be required to continue for at least 12 hours.

Participant type(s)
Patient

Age group
Child

Upper age limit
16 Years

Sex
Both

Target number of participants
1,500

Key exclusion criteria
1. Children born pre-term and who are < 36 weeks corrected gestation
2. Children with diabetes mellitus
3. Children with an established or suspected diagnosis of an inborn error of metabolism
4. Children for whom treatment withdrawal or limitation of intensive care treatment is being considered
5. Children who have been in a PICU for more than 5 days in succession
6. Children admitted to a PICU who have already participated in the CHIP study during a previous PICU admission

Date of first enrolment
01/02/2007

Date of final enrolment
30/04/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Royal Brompton Hospital
London
United Kingdom
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Sponsor information

Organisation
Royal Brompton & Harefiled NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.rbht.nhs.uk

ROR
https://ror.org/02218z997

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/02/2010		Yes	No
Results article	results	09/01/2014		Yes	No
Results article	results	01/04/2014		Yes	No