

# Control of hyperglycaemia in paediatric intensive care

<b>Submission date</b> 23/01/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 24/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/06/2016	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

## 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  
d.macrae@rbht.nhs.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
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](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

**Study type(s)**

Treatment

**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  $\leq 10$  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(s)**

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 (VFDs) brings together these two outcomes. Schoenfeld et al define ventilator free days (VFDs) as:  $VFD=0$  if the child dies before 30 days;  $VFD=(30-x)$  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.

**Key secondary outcome(s)**

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)

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Upper age limit**

16 years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

Royal Brompton Hospital

London

United Kingdom

SW3 6NP

**Sponsor information****Organisation**

Royal Brompton & Harefield NHS Trust (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, Health Technology Assessment (HTA), HTA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	09/01/2014		Yes	No
<a href="#">Results article</a>	results	01/04/2014		Yes	No
<a href="#">Protocol article</a>	protocol	05/02/2010		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes