CHiP

NEWSLETTER

Control of Hyperglycaemia in Paediatric intensive care

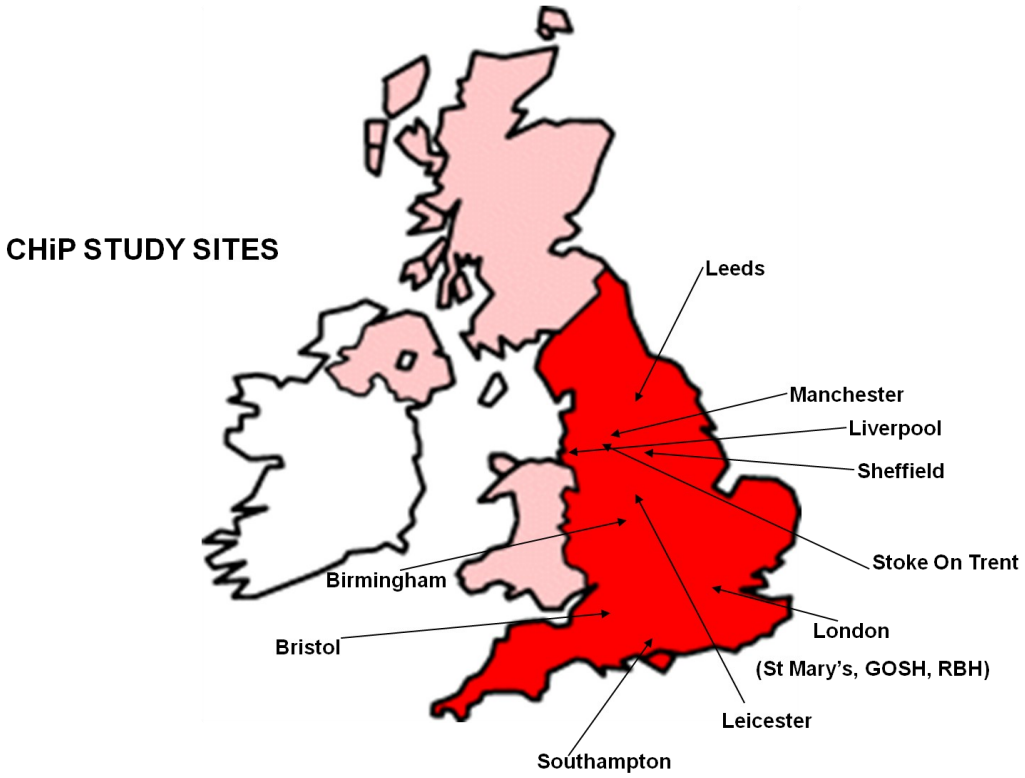
No. 3

August 2009

Recruitment

Thank you to everyone!

CHiP is now in its 2nd year with 12 study sites recruiting



Since the first patient was enrolled in Southampton on the 4th May 2008 over 430 participants have been recruited to CHiP.

Recruitment has however been slower than expected due to a number of factors including late site start ups. We now effectively have 14 units within 12 sites all actively recruiting to CHiP. We hope that with continued commitment in all units, CHiP will be successful in reaching its recruitment target.

This is extremely important not just for CHiP but also for any other trials which may follow. Funding for studies in PIC will become less available if we are not able to point to a 'good' track record."

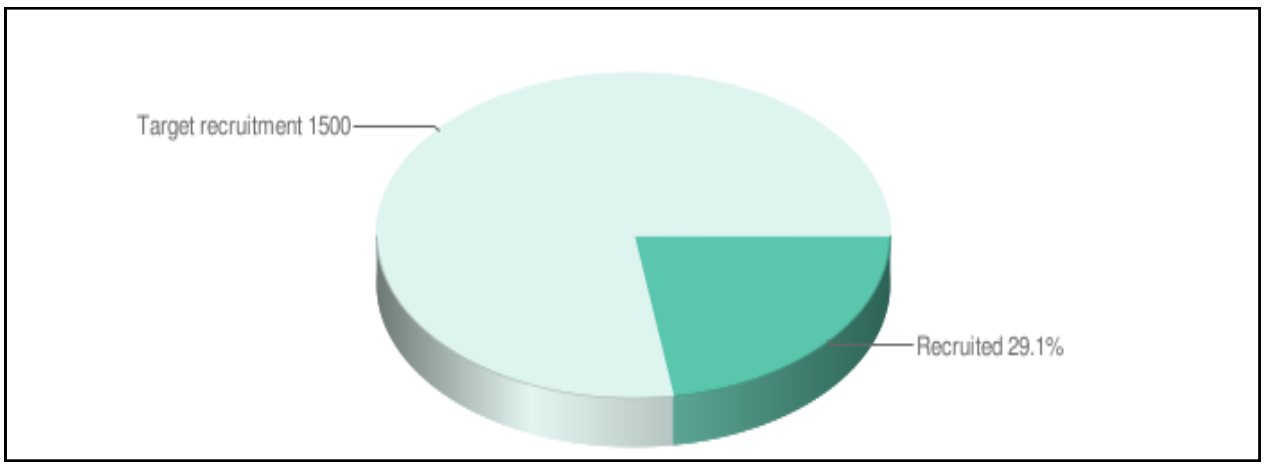
ISRCTN61735247

CHiP Trial Recruitment by site

SITE	Cardiac patients	Non-cardiac patients	Total recruited
Birmingham Children's Hospital	61	20	81
Bristol Royal Hospital for Children	42	15	57
Great Ormond Street Hospital	18	35	53
Leeds General Infirmary	3	0	3
Royal Brompton & Harefield NHS Trust	45	0	45
Royal Liverpool Children's NHS Trust	34	15	49
Royal Manchester Children's Hospital	N/A	32	32
St Mary's Hospital	N/A	26	26
Sheffield Children's NHS Foundation Trust	N/A	17	17
Southampton General Hospital	31	34	65
University Hospital of North Staffordshire	N/A	2	2
University Hospitals of Leicester NHS Trust	6	0	6
TOTALS	**240**	**196**	**436**

Tips to help recruitment……

- Sites should screen patients at least once each day.
- All patients admitted to your PICU/CICU (not HDU) should be recorded on the screening log whether or not they meet inclusion criteria.
- PIs must involve the whole team; a dummy screening log included on the daily ward round will be invaluable in highlighting a potential patient.
- Continue to train and update PICU staff so that they are familiar with the trial, feel ownership of it and can alert the appropriate people when potential patients are admitted to the unit.



Interesting recently published studies

The NICE Sugar Study (1) is a large multicentre study of TGC in adults which unlike the landmark 'Leuven' studies, showed a slightly higher mortality rate in the TGC group. It is important to understand that in this study 'Control' patients were in fact more 'tightly controlled' (<10 mmol/l) than in previous studies (<12 mmol/l) which may explain differing results. A meta-analysis (2) published simultaneously with NICE Sugar is worth reading, and points to possible benefits of TGC in sub-populations, which however need to be further studied and defined.

The 'Paediatric' Leuven Study (3) was a single centre study of TGC in paediatric intensive care. There were fewer deaths with TGC (3%) than with Control (6%) treatment. TGC also improved lengths of stay and some other important outcomes. These are encouraging findings BUT CHiP is still very important as:

- We are using different (we think safer) low glucose limits and have seen substantially less hypoglycaemia than reported by Vlasselaers.
- Our study is multicentre and therefore a truer test of the 'diffusibility' of TGC in 'real world' PICUs
- If we meet recruitment targets, we have the power to determine effects in both cardiac surgical and non-surgical groups
- We have planned clinical and economic follow-up

CHiP is more important than ever. The sooner we complete, the sooner we will answer our important research question. Thanks to you all!!!

Duncan

(1)Finfer S, NEJM 2009 360 : 1283-1297
(2)Griesdale DE, CMAJ 2009 180 : 821-827
(3)Vlasselaers D, Lancet 2009 373: 547-556

DATE FOR YOUR DIARY!

2nd CHiP Trial Study Day

To be held at Birmingham Children's Hospital Education Centre on October 19th 2009. 10:30 -18:00

This is for all CHiP funded nurses and actively involved MCRN nurses. The purpose of this day is to provide a comprehensive update on the Trial to date. It will be an opportunity to get together again with your CHiP nurse colleagues and share experiences. Suggested topics are: Study update, experiences shared, a critique of a tight glycaemic paper, a session with an endocrinologist, result's from a recent glucose audit...

(Lunch and Travel Expenses will be provided)

Keep up your hard work!

A Positive Approach to Obtaining Informed Consent

Ensuring informed consent is obtained is one of the most important ethical requirements of clinical trial investigators. The high level of emotional stress that the parents/guardians are under can make it difficult to consider fully the risks/benefits of trial participation.
As a researcher there are many things that you can do to ensure that you are truly obtaining informed consent:

- Approach the parent/family with facts in hand.
- Conduct the interview in a quiet room or private area where the family can focus on the discussion.
- Provide the family with a blank piece of paper and pen to write down any questions they may have.
- Bring multiple copies of the study information sheet to the informed consent interview, so that all family members can view and make notes on the document.

Keeping up to date

To ensure you are up to date with the latest regulations and clinical trial procedures, it is recommended that anyone involved in a clinical research study should undertake GCP training every two years. The NIHR CRN offers training courses that are free of charge to anyone working on CHiP. CHiP will reinburse travel expenses for CHiP funded research nurses to attend GCP and consent training courses. Below is a selection of courses that may be of interest. Unfortunately CHiP is not able to fund the travel or time to attend all of these courses.

Course name and date	Location
NIHR CRN Governance Training	
GCP & the EU Directive Online	
Available now	
Valid Informed Consent Online	
Available now	
NIHR CRN Research Knowledge and Skills Training	
Communication and Consent in Paediatric Research (Part 1)	
24 September 2009	*London*
Communication and Consent in Paediatric Research (Part 2)	
15 October 2009	*Bristol*
Patient Information for Parents and Children	
5 November 2009	*Birmingham*
Understanding Paediatric Research Advanced	
8 October 2009	*Manchester*
Topic specific courses: MCRN	
Paediatric Medicines: Pharmacology, Formulations and Regulations	
11 November 2009	*Manchester*
Patient Information for Parents and Children	
5 November 2009	*Birmingham*
Understanding Policy, Achieving Quality in Paediatric Research	
14 October 2009	*Manchester*

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