Control of
Hyperglycaemia in
Paediatric intensive care

PATIENT INFORMATION LEAFLET

For parents/guardians of children likely to have cardiac surgery

CARDIAC

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1. Introduction

Your child is being invited to take part in a nationwide medical research study called CHiP. This information sheet gives you details about the study. We explain why we are asking you to think about taking part, and what you can expect if you agree. Please remember, you do not have to take part and the quality of your child's care will not be affected in any way, whatever you decide.

This information sheet is in two parts:

Part I tells you about why we are doing this study and what will happen if you agree for your child to take part.

Part 2 gives you some more information about how research studies like CHiP are run.

PART 1

2. Why is a study needed?

When babies, children and adults are in intensive care, the levels of sugar in their blood can go up. This is called hyperglycaemia. It can happen because they have had a serious illness, an injury, or surgery. In Paediatric Intensive Care we take small samples of blood regularly. We use these to check sugar levels. Babies and children with high blood sugar are usually treated with a drug called insulin, but only if the blood sugar reaches quite a high level. We measure the level of sugar with a scale called millimoles per litre, shortened to mmol/L. When the level reaches 12 (mmol/L), we would say that this is too high and should be treated.

In adults, some research has suggested that controlling the blood sugar levels *tightly* may speed recovery time. *Tight* control means checking the blood more often. If the sugar level is going up, we give insulin at around level 7, rather than waiting until it goes up to level 12 (we will tell you more about insulin later in this leaflet). This *tight* control may also be a promising treatment for children, but we do not know whether children will respond in the same way as adults.

If blood sugar levels are raised above normal this is called hyperglycaemia

3. Why has my child been chosen for this study?

Your child has been chosen for this study because s/he is likely to have a heart operation. After the operation s/he may need to spend a few days in the Paediatric Intensive Care Unit being helped to breathe by a machine called a ventilator and medicines to support his/her blood pressure. We are hoping that 1500 children on a ventilator will take part in the CHiP study. Doctors and nurses from Paediatric Intensive Care Units in ten hospitals are helping with the study. You have been given this information leaflet and asked if you would like to join the CHiP Study because your child is in one of these ten hospitals.

4. What is the study testing?

We are comparing two different ways of controlling blood sugar levels using insulin. Insulin is a drug that is used by lots of people who have diabetes. It is also used for

patients like your child who are in intensive care. It helps to control the level of sugar in their blood. Although we would use insulin, this does not mean that your child has diabetes.

We are doing the study to help us find out whether it is better to *tightly* control the sugar levels by giving insulin when the blood sugar rises above level 7 or to treat only when the sugar level reaches level 12. For each approach there might be advantages and disadvantages. The best way of finding out is to carry out a randomised study such as the CHiP Study. A randomised study is a way of comparing the effects of the two approaches. This is a good and a fair test of the two approaches.

We want to test whether tight control of blood sugar levels will help children and not do any harm.

5. What will happen to my child if we agree to take part?

For the CHiP Study, half of the children will be treated using one approach, *tight* control using insulin to keep the blood sugar between level 4 and 7. The other half will be treated using the *usual* approach, to treat with insulin if the sugar goes up to level 12 on two checks, tested 30 minutes apart. A computer is used to put each child into one of these two groups. It does this in a random way. This means that it uses chance, a bit like flipping a coin, to organise the two treatment groups.

A small blood sample will be taken without any pain from one of the drip lines which has already been inserted as part of the care of your child. It will be used to measure the level of blood sugar. Whichever treatment group your child is in, the insulin (if used) is given through a tube into a vein. Treatment if necessary will take place during the time your child is in Intensive Care. If your child is in the tight control group s/he is likely to receive more insulin than children in the usual treatment group. If his/her blood sugar levels do not go up then insulin will not be given, whichever group s/he is in.

Information about all of the children in the study will be collected while they are in hospital. The study team do not want to lose contact with you afterwards. Once you have taken your child home, the Study Manager from the CHiP Data Co-ordinating Centre in the London School of Hygiene and Tropical Medicine will write to you. She will ask if you will help with some more information later, as the CHiP Study team need to try to follow-up everyone who has been in the study. It would also be very helpful if you would agree that your child's name could be registered with the NHS Information Centre and the NHS Central Register. This would make it easier for the study team to contact you in the future and provide the study team with information about your child's health status even if you move house.

If you are happy for your child to take part in the CHiP Study, and are comfortable with the explanations from the doctors and nurses at this hospital, you will be asked to sign a consent form. We will check with you again if your child is admitted to

paediatric intensive care and becomed eligible for the study, to make sure that you are still happy to go ahead. A member of staff from the Unit will then make a telephone call to the study centre. The staff member will give the centre some details about your child and find out which study group your child will be in. This will tell the intensive care staff which of the two treatment approaches they will follow if sugar levels go up.

6. Does my child have to take part?

No, it is up to you to decide whether or not your child takes part. You are free to withdraw at any time without giving a reason. This would not affect the quality of care your child receives.

7. What treatment will my child get if s/he does not take part?

We will give your child the same treatment that all patients in paediatric intensive care would receive. This means that we would give insulin if the blood sugar levels go up to level 12 on two tests. The tests would be taken 30 minutes apart. If the blood sugar levels do not go up, then we would not need to use any insulin.

8. What are the possible benefits to my child from taking part?

We are doing this study because we do not know whether *tight* control of blood sugar produces better results. Some studies carried out in adults in intensive care have shown that patients treated with *tight* control of blood sugar do better but others have not shown any benefit of *tight* control. If children benefit in the same way as adults did in some of these studies, then *tight* control of blood sugar levels may be helpful in speeding up recovery time. We cannot promise the study will help your child but the information that we get might help other children in the future.

9. What are the possible side effects of the treatment and possible risks of taking part?

There is a possibility that for children in the *tight* control group, giving insulin at an earlier stage might mean that the level of sugar in the blood will drop BELOW normal. This is called hypoglycaemia (the opposite of hyperglycaemia where sugar levels are high). Mild hypoglycaemia can cause confusion and/or dizziness. Severe hypoglycaemia could cause brain damage but only if left untreated for a long time. Be reassured that the doctors and nurses in the CHiP Study will be carefully watching your child. If your child shows signs of hypoglycaemia, this will be picked up very quickly while still very mild and prompt action will be taken to treat it. The staff will stop the insulin treatment straightaway and will give extra sugar either by mouth or as a sugar solution through a drip.

For the children who are in the *usual* care group, who will receive insulin if the blood sugar level goes up to 12, the possible risks are different. For them there is the possibility that their sugar levels might get too high. This can affect how the organs of the body work, but as we have said, all the children in the study will be very carefully monitored. There are not thought to be any other risks to your child from taking part in the study.

10. Are there any other possible disadvantages?

If your child is in the *tight* control group he/she is likely to have more blood samples taken than if in the *usual* care group

Also we do appreciate that we are asking you to consider a research study when you are naturally feeling worried about your child and that this might be adding to your stress now.

11. What if there is a problem?

If you have any complaint about the way you or your child is dealt with during the study or feel that you had suffered any sort of harm, this will be addressed. The detailed information about this is given in Part 2.

12. Will taking part in the study be kept confidential?

Yes, all information about your child's participation in the study will be kept confidential. The details are included in Part 2.

13. Involvement of the Family Doctor (GP) and Health Visitor

With your permission, we will let your GP and health visitor know that your child is taking part in the study.

14. Your contact people for the study in this hospital are:

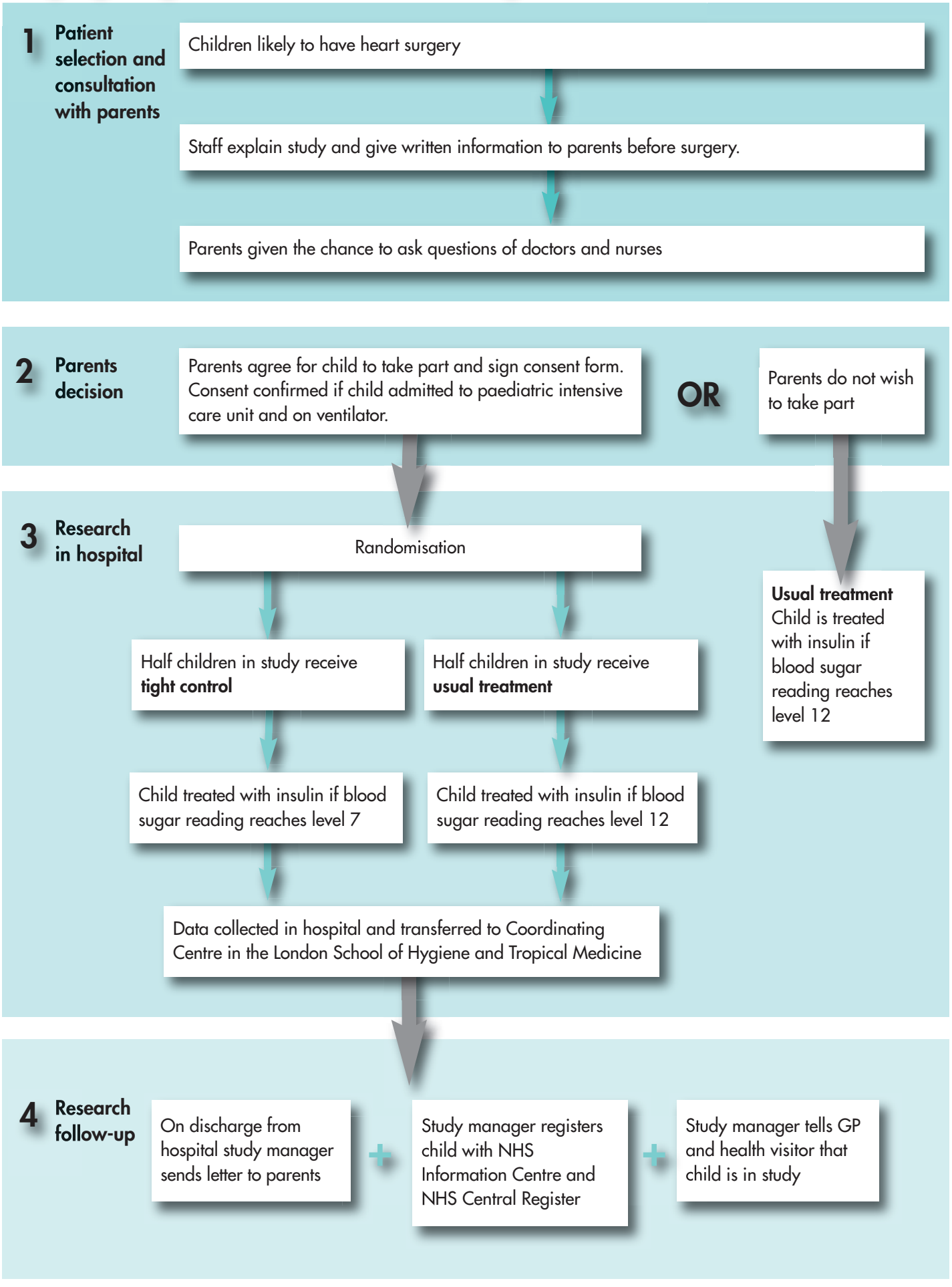
If the information in Part 1 has interested you and you are considering taking part in the CHiP Study, please continue to read the additional information in Part 2 before making a decision.

Principal Investigator name
Hospital address
tel:

CHiP Research Nurse name
CHiP Research Nurse
Hospital address
tel:

Complaints Manager name
Complaints Manager Title
tel:

Step by Step Guide to the CHiP Study



PART 2 *Part 2 gives you some more information about the conduct of research studies. Please read it before you agree to take part in the study.*

What will happen if I don't want my child to carry on with the study?

If you decide to take part in the study but then change your mind, just tell the research nurse or doctor. We will stop collecting information about your child and if you wish, any information we have already collected can be destroyed. If your child is in the *tight* control, s/he will instead be given usual care which is to give insulin at level 12. If your child is in the *usual* care group nothing will change.

Will my child's taking part in the study be kept confidential?

All information about your child (including your contact details) which is collected for the study will be kept securely and strictly confidentially within the study team (the hospital and the Data Co-ordinating Centre at the London School of Hygiene and Tropical Medicine), and your child's doctor (GP) and health visitor. We will not use your child's name in any analysis or in any reports that we write. The study team are responsible for analysing, storing and eventually destroying the data according to guidelines set by the National Health Service Research & Development Unit. Information will be kept for up to 15 years at the study centre.

What will happen to the results of the research study?

The results will be available when all the children have been followed up and the results analysed. This is likely to be in 2012. The research will be published in a scientific journal and the results publicised widely. A summary of the research and details of how to find the scientific publication will be posted on the study website (website www.chip-trial.org.uk). A summary of the results will be sent to parents if you let the Study Manager know that you would like to have this.

What if there is a problem?

If you have a concern about any aspect of the study you should ask to speak to Helen Betts (Lead Research nurse tel: 07854 980 072 or to the Chief Investigator, Dr. Duncan Macrae 020-7351 8546) who will do their best to answer your questions. If you remain unhappy and wish to make a formal complaint, you can do this through the NHS Complaints Procedure at this hospital (name and tel number to inserted for each collaborating hospital). The Royal Brompton and Harefield Trust is the sponsor of this research project. In the very unlikely event that your child is harmed due to someone's negligence, then you may have grounds for legal action against the sponsor of the research or NHS Trust but you may have to pay for it. This is the normal procedure, whether or not there is a research study. If you wish to complain about any aspect of the way your child has been approached or treated during the course of this study, all the normal health service complaints mechanisms are available to you.

Who is organising and funding the research?

The study is funded by the Health Technology Assessment Programme of the NHS. This study is co-ordinated by the Royal Brompton and Harefield NHS Trust and the London School of Hygiene and Tropical Medicine (LSHTM). The Royal Brompton Hospital is responsible for the conduct of the study. The research grant from the Health Technology Assessment Programme pays for the employment of research nurses and the study team at the LSHTM.

ChiP Study Team

Dr Duncan Macrae, Chief Investigator CHiP Study
Royal Brompton Hospital
Tel: 020-7351 8546
Email: d.macrae@rbht.nhs.uk

Laura Van Dyck/Lucy Brooks, Study Manager
CHiP Data Co-ordinating Centre
London School of Hygiene and Tropical Medicine
Tel: 020-7927 2075
Email: Laura.VanDyck@lshtm.ac.uk/Lucy.Brooks@lshtm.ac.uk

This study was given a favourable ethical opinion for conduct in the NHS by the Brighton East Research Ethics Committee.

Thank you for taking the time to read this information