Control of
Hyperglycaemia in
Paediatric intensive care

PATIENT INFORMATION LEAFLET

For young people likely to have heart surgery

YP

1. Introduction

We are asking if you would take part in a nationwide medical research study. This information sheet gives you details about the study. We explain why we are asking you to consider joining in. Please read this leaflet carefully. Talk about it with your parents/guardians and also with the doctor or nurse if you want to. Please remember that you do not have to take part.

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 to join in.

Part 2 gives you some more information which you will need if you want to take part.

PART 1

2. Why are we doing this research?

Young people usually go into a Paediatric Intensive Care Unit after a heart operation. The levels of sugar in their blood can go up. This is called hyperglycaemia. It can happen because they have had an operation. In Paediatric Intensive Care, we take small samples of blood regularly. We use these to check sugar levels. Young people as well as 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 goes up to 12 (mmol/L), we would say that this is too high and should be treated.

Research with adults makes us think 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 a drug called insulin at around level 7, rather than waiting until a higher level is reached. This *tight* control may also be a promising treatment for young people. However we do not know whether young people will respond in the same way as adults.

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

3. Why have I been asked to take part in this study?

We have given you this information leaflet because you may have an operation on your heart. After the operation you may need to spend a few days in the Paediatric Intensive Care Unit as you recover. You may need the help of a breathing machine (ventilator) and medicines to support your blood pressure. If you are on the ventilator you may be the sort of patient who could take part in this study. We are inviting 1500 children and young people to take part. Doctors and nurses from Paediatric Intensive Care Units in ten hospitals are helping with this study.

4. What is the study testing?

We are testing two different ways of controlling blood sugar levels using insulin. Insulin is a drug that helps to control the level of sugar in the blood. It is also used by people who have diabetes. Although we might use insulin for you, this does not mean that we think you have diabetes.

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

We want to test whether tight control of blood sugar levels will benefit young people and not do any harm.

5. What will happen to me if I agree to take part?

For CHiP half of the young people will be treated using one way. That is *tight* control using insulin to keep the blood sugar between level 4 and 7. The other half will be treated in the *usual* way. That is to treat with insulin if the sugar goes up to level 12 on two tests. A computer is used to put each young person 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 this tube which has already been put into your vein as part of your care. It will be used to measure the level of blood sugar. Whichever treatment group you are in, the insulin (if used) is given through this tube into a vein. Treatment will take place during the time you would be in the Intensive Care Unit. Young people in the *tight* control group are likely to receive more insulin than young people in the *usual* treatment group. If the blood sugar levels are not raised then insulin will not be given, whichever group you are in.

Information about you will be collected while you are in hospital. After you leave hospital the CHiP Study Manager from the Data Co-ordinating Centre in the London School of Hygiene and Tropical Medicine will write to your parents to follow-up your progress. We are also asking your parents if they will agree for the study team to give your name to the NHS Information Centre and the NHS Central Register. This will make it easier for the study team to contact you in the future even if you move house.

If you are admitted to the Paediatric Intensive Care Unit your parents will be asked if they still agree for you to be in the study. The staff will then make a telephone call to the study centre. They will give your details and find out which treatment group you are in.

6. Do I have to take part?

No it is up to you and your parents. If you are happy to take part, and have had your questions answered you will asked to sign the form at the end of this leaflet. If you do not take part it would not affect the quality of care that you receive.

7. What treatment will I be given if I do 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 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 have shown that patients treated with *tight* control of blood sugar do better but others have not shown any benefit of *tight control*. If young people benefit in the same way as adults did in some of these studies, then *tight* control may be helpful in speeding recovery time. We cannot promise the study will help you. However the information we get might help other young people in the future.

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

For young people in the *tight* control group, there is a possibility that blood sugar levels 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 you. If you show signs of hypoglycaemia, this will be picked up very quickly while it still very mild. The staff will stop the insulin treatment straightaway and will give you extra sugar either by mouth or as a sugar solution through a drip.

For young people 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 go too high. This can affect how the organs of the body work, but as we have said, you will be very carefully checked. There are not thought to be any other risks to you from taking part.

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

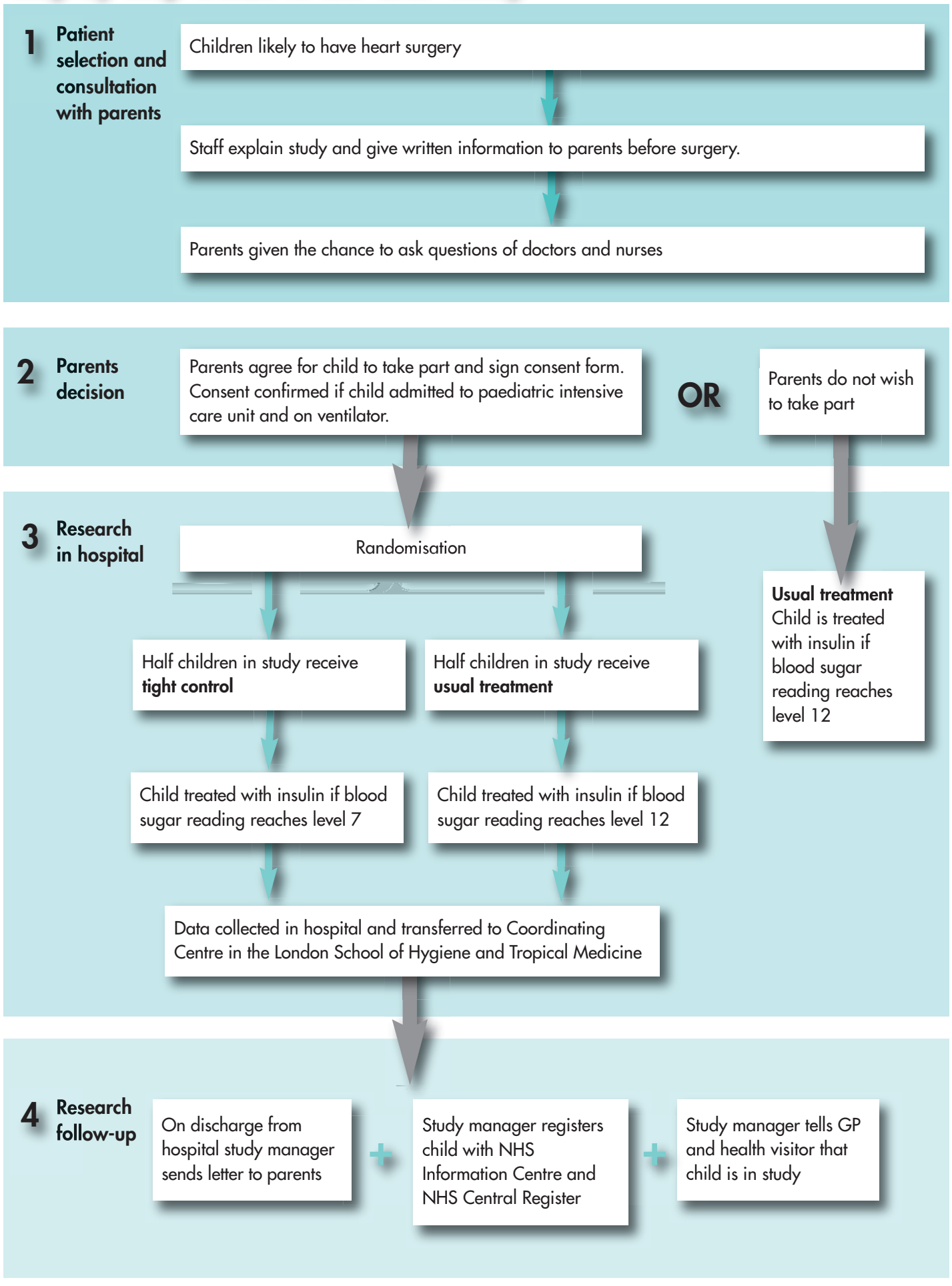
Principal Investigator name
Hospital address
tel:

CHiP Research Nurse name
CHiP Research Nurse
Hospital address
tel:

Complaints Manager name
Complaints Manager Title
tel:

Thank you for reading so far. If you are still interested please go to Part 2.

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 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 before you have your operation. Your parents may change their mind after you have had your operation. We will stop collecting information about you. If you wish, any information we have already collected can be destroyed. If you are in the *usual* care group nothing will change. If you are in the *tight* control group you will instead be given *usual* care which is to give insulin at level 12.

What if there is a problem or something goes wrong?

Information about who to contact if there is a problem is given in the information sheet for parents.

Will anyone else know that I am in a research study?

Yes – the study team in this hospital and at the Data Co-ordinating Centre at the London School of Hygiene and Tropical Medicine will know that you are taking part in the study. We will also tell your family doctor. If you agree to take part in the research, any of your medical records may be looked at to check that the study is being carried out correctly.

What will happen to the results of the research study?

The results will not be available until 2012 when everyone taking part has been followed up and the results analysed. The research will be published in a scientific journal and the results publicised widely. A research summary will be posted on the study website www.chip-trial.org.uk. A summary of the results will be sent to you and your parents if you let the Study Manager know that you would like to have this.

Who is organising and funding the research?

This study is run by the Royal Brompton and Harefield NHS Trust and the London School of Hygiene and Tropical Medicine. The study is funded by the Health Technology Assessment Programme of the NHS. The Royal Brompton Hospital is responsible for the conduct of the study. The doctor who is co-ordinating the study at this hospital is not being paid to include you in the study.

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Who has reviewed the study?

Before any research goes ahead it has to be checked by an Ethics Committee to make sure that the research is suitable. This study has been checked by the East Brighton Ethics Committee.

Thank you for taking the time to read this information. Please ask any questions if you need to.