NHS Guy's and St Thomas' NHS Foundation Trust
King's College London
King's Health Partners
NHS Great Ormond Street Hospital for Children NHS Foundation Trust

ATT- Heart:

An open label, single-centre dose escalation trial, investigating the safety and feasibility of **A**utologous **T**hymus derived regulatory **T** cell treatment for the prevention of cardiac allograft vasculopathy in children receiving **Heart** transplant.

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CHILDREN PATIENT INFORMATION SHEET (Guide Age: 7 - 10 year olds)

Introduction:

Would you like to help test a new medicine in a clinical trial?

Before you decide, it is important for you to understand what this project is about, and what will happen to you if you take part.

Please read this leaflet carefully and ask us about anything that you do not understand.

What is the study for?

We are trying to collect information on a new type of medicine called TR006 that will be given to children who are getting a heart transplant.

TR006 is made using your own cells and will be given back to you around 3 months after you have had your heart operation.

We want to test this medicine to try to stop a condition called Cardiac Allograft Vasculopathy. This is also known as CAV and it can affect the health of the new heart as people get older.

We want to find out about new treatment options for CAV to help treat people who are given new hearts help their new heart stay healthy for longer.

Why have you been invited?

We have invited you because you are on a waiting list for a heart transplant.

Do I have to take part?

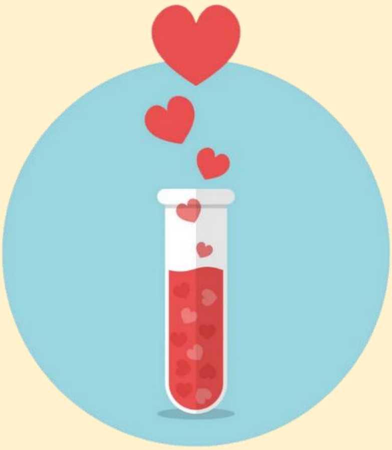
- You do not have to take part in this study if you do not want to.
- If you decide not to take part, it will not affect how your doctors treat you.
- If you do decide to take part, and your parents or carers agree, you will both sign a form to say you are happy to take part.
- You can change your mind at any time without saying why.

What information will we collect from you?

For at least two years, the study will collect information about you.

We want to know how you are doing after your heart transplant, the medical treatment and tests you need, and how you are feeling.

A lot of the information the study collects will come from your normal hospital visits, although you will have to make a few extra visits to the hospital for the study.



When you have your normal blood tests, your doctor may ask you to give some extra blood samples for the study team to look at. Blood tests can hurt a little bit but you can have some numbing cream or spray to help with this.

As part of your normal care, the doctors will collect small pieces of your heart muscle. This will be done whilst you are asleep so you will not feel it. The muscle pieces are checked under the microscope to see how healthy it is.

These blood tests and heart samples will let the study team know how your heart is doing, and how it reacts to the new medicine.

How is the new medicine given?

If you agree, you will have the new medicine (also called TR006) when you come to hospital. Before we give it, a doctor will check you and your heart to make sure it is okay. The medicine is given through a small plastic straw in your arm. Putting the plastic straw in can hurt a bit, like when you have a blood test. Numbing cream or spray can sometimes help with this. It takes around 30 mins for the medicine to be given and we will be looking after you the whole time.

We will look after you in hospital after the medicine is given for at least one night to make sure everything is okay. The day after the medicine we will check your heart and blood tests again before you go home. You should tell us if anything does not feel right when you are in hospital.

What happens when the research stops?

Once the study is over, you will continue to receive your usual health care with your normal doctor.

What will happen to my information?

We will need to use information from you and your health records for this study.

People will use this information to do the study or to check your records to make sure that the study is being done properly.

You can find out more about how we use your information by:

- Asking Professor Michael Burch (Email: Michael.Burch@gosh.nhs.uk)
- Asking the GOSH data protection officer at: your.data@gosh.nhs.uk
- Looking at the, "What is GDPR," video at: https://www.youtube.com/watch?v=VlI6V1MgZgY
- Asking the study team if you have any questions.

What will happen to the results of this study?

The results of the study may be shown at science meetings and written about in medical research magazines. This will happen in a few years from now.

Your doctor will be able to tell you about how the research is going.

Your data will have a code number and so we will write our reports in a way that no-one outside of your treating team can work out that you took part in the study,

How to ask questions and contact us:

You can ask about the study at any time and this is totally OK.

If you have any questions at all you can ask one of the people looking after you or your family. We will do our best to answer any questions you have.

The Study Team at your hospital can be reached by asking for:
Local Study Team Contact:

Email:

Telephone Number:

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CHILDREN PATIENT ASSENT FORM (Guide Age: 7-10 year olds)

For individuals not legally able to agree to consent. To be signed alongside a Parent/Guardian Consent Form.

Please initial box to agree WB

Or cross if you do not agree ☒

I have read the study information ☐

I was able to ask questions about the study ☐

I was told what I wanted to know ☐

I know that I can stop taking part in the project at any time and it will not affect how I am treated in the hospital and the nurses and doctors will not mind at all ☐

I am OK to give some cell, blood and heart samples for research ☐

I want to take part in the ATT-Heart study ☐

Your name:

Your signature:

Date:

When completed: 1 copy for patient; 1 copy for medical notes; 1 (**original**) to be kept in Investigator Site File.