ATT-Heart

YOUNG PERSON PATIENT INFORMATION SHEET **(Guide Age: 11-15 year olds)**

Introduction:

Title of Project: ATT- Heart.

Full Name of Project: 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. (Also called the **ATT Heart** Trial)

Name of Researcher: Professor Michael Burch (Paediatric Cardiologist based at Great Ormond Street Hospital (GOSH), London).

- We would like your help with a research project (also known as a study or trial).
- Please take time to read this leaflet carefully and discuss it with others if you wish.
- It is OK to ask us to explain something better, just let us know.
- Take time to decide if you wish to take part in this research project/study.

Thank you for reading this information sheet.

Why are we doing this study?

We want to learn more about a new type of medicine that will be given to children who are receiving a heart transplant. We want to give this medicine in order to prevent a condition called Cardiac Allograft Vasculopathy (which is also known as CAV).

CAV is a condition that affects transplanted hearts. It causes the blood vessels that supply blood to the heart muscle to become narrowed and this can affect how well the new heart pumps. We want to learn more about this new treatment for CAV that may help treat children who have heart transplants so that their new heart can stay healthy for longer.

All children who take part will be have check-ups with our team for at least two years to look at the safety of this new type of medicine. If it is safe, in the future we can do a bigger research project and involve more children.

Why have you been invited?

We have invited you because you are on a waiting list for a heart transplant and if you would like to take part, we can make this medicine to give to you after you have had a new heart.

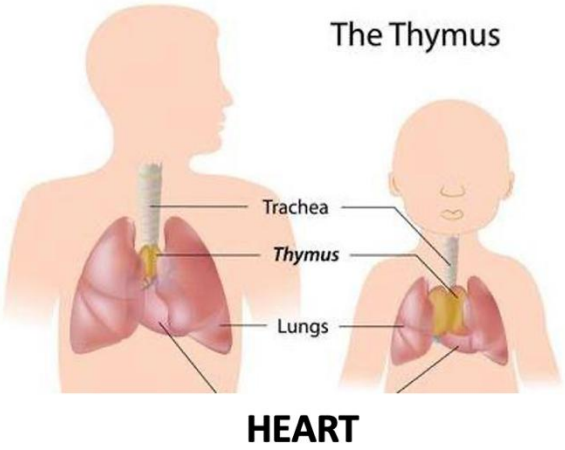
About your body.

Here is a little bit about your body that will help you understand the science behind the medicine being used in the study.

Cells: These are the smallest building block of every living thing on our planet, including you. The cells used for this medicine are part of your **immune system**.

Immune system: This is the body's defence system against germs. The immune system includes cells that can control how we respond to bacteria, viruses and other things that our body does not recognise.

Thymus: This is a butterfly shaped gland that sits in front of the heart and major blood vessels (see picture) and one of its jobs is to make special type of cells called Regulatory T-cells (or Tregs) that can be released into the blood system. Tregs help the immune system in the body from working too hard against the new heart.



What is the medicine being used in the study?

The medicine being used in this study will be known as TR006.

TR006 is a new type of medicine that is made from your own cells which will be collected from your thymus gland.

Some or all of the thymus is normally removed during heart surgery. For this project, if you agree, your thymus will be taken out during your transplant surgery and sent to a special lab at Guys Hospital (in London) who will work on your thymus cells to make TR006 for you.

Once the TR006 is made, a few months after your heart transplant, it will be given to you in one go, using a plastic straw (also called a cannula) in your arm. This process is called an infusion. It should take around thirty minutes for the whole treatment to finish and we will be looking after you closely throughout. You will then stay in hospital overnight and the study team will look after you until the next day to make sure that everything is okay with you. If something does not feel right at the time or after, you should tell us.

What are the possible benefits of taking part?

We cannot promise that this study will help you. The medicine that is given may protect a transplanted heart from CAV, however we do not know this for certain. You may not benefit from taking part in this study but the information gained may improve the treatment options available to other children receiving a new heart in the future to help prevent CAV.

Are there any risks to me if I take part?

If you decide to take part in this study, most of the check-ups will happened at the same time as your usual medical appointments with the Transplant Team at GOSH. There will be a few extra times where you have to come to the hospital for research-related visits.

This is the first time that TR006 will be tested in children in the UK. So, there may be risks we do not know about yet and they could be serious.

We think the risks of TR006 are similar to those seen if someone has an allergic reaction to a blood transfusion. An allergic reaction can occur when somebody's immune system overreacts to a certain substance.

Because TR006 is made from your own cells, the risk of such a reaction is less likely compared to a reaction from blood transfusion (when blood is collected from other people or blood 'donors'). Reactions to blood transfusions are uncommon but they can look like: itchy skin, swelling of hands, arms, feet, ankles and legs, dizziness and headaches, high temperature, chills or shivering.

Blood tests will mainly be used as part of your normal medical care and are important to check that everything is OK with you. They can be a bit uncomfortable and can cause some bruising or itching, but this is mild. Inserting the plastic straw (or cannula) in your arm before giving your TR006 can feel similar to a blood test and can hurt a little. We can give you some numbing cream or spray to help with this.

Your doctor may ask you to give some extra blood samples which will be taken at the same time as your usual medical blood tests. These extra blood samples are for the study team to look at and they will give us information of how your body is built, and how it reacts to treatment with TR006.

As part of your normal medical care after transplant, the medical team will collect small samples of your new heart to make sure things are going OK after your heart transplant. This is called a cardiac biopsy and this is usually done whilst you are asleep (under general anaesthetic) The process used to collect these heart tissues samples is considered low-risk but some of the risks may include: bruising, bleeding, damage to blood vessels or the heart.

The study team may use some of these heart samples to look at your heart and to also see how it reacts to treatment with TR006.

Coronary angiograms and X-ray guided cardiac biopsies are part of your normal care. An explanation about these procedures are below (on page 7). If you take part in this study you will not undergo any additional angiograms or biopsies. These procedures use ionising radiation to form images of your body and provide your doctor with other medical information. Ionising radiation may cause cancer many years or decades after the exposure. The chances of this happening to you are the same whether you take part in this study or not.

The important thing is that if you do decide to take part in the study and if you feel unwell at any point, please tell someone. You will be given a contact card that has the details of the study team and so you can speak to them whenever you want to.

Only Boys Need to Read this Section

If you are sexually active and your female partner could become pregnant, you should let her know that you are in this study. We do not know how TR006 will affect the health or development of an unborn baby and it could be harmful. And so the study team wants to make sure that no one who is or going to be pregnant (having a baby), is exposed to this medicine.

If your partner is already pregnant when you start in this study, or if you are having sex with a girl who becomes pregnant once you have taken the study medicine, you should tell your study doctor or the study staff right away and they will advise you about what you should do.

If your partner becomes pregnant while you are taking part in this study, the study doctor or the study staff will recommend that you tell your parents/guardian about the pregnancy. The study team will also need to collect information on how things progress after the pregnancy.

Only Girls Need to Read this Section

If the study medicine is taken by a girl who is pregnant (having a baby) or breastfeeding, it could harm the unborn baby. Therefore, the study team needs to make sure that no one who is pregnant, or breastfeeding is given the study medicine.

It is possible for a girl who has had her first menstrual period and has started sexual activity to become pregnant. If you have had your first menstrual period, you will be asked to take a urine pregnancy test (known as a dipstick test) at various points when you agree to be in the study. This is needed whether you have had sexual activity or not. The study team will let you know if you have a positive pregnancy test at any point. If you are pregnant you will not be allowed to take part in the study, and we will advise you to get medical care for your pregnancy.

If you start being sexually active during the study, you must use an effective way of preventing pregnancy. The study team can advise you about the birth control pill, injections or patches, or other contraceptive methods that are allowable for the study.

If you are having sex but are not sure if the type of sex you are having can cause you to get pregnant, please ask the study doctor or study staff to explain. If you could become pregnant, you must talk to your study doctor about the type of birth control you are using. You can talk to the study doctor about contraception without your parents being present if you would prefer. As you probably know, the best way to avoid getting pregnant is to not have sex.

If you become pregnant or think you might be pregnant during the study, please tell the study doctor or the study staff. The study doctor or the study staff will be able to support you with any questions you have. They may also refer you to your regular doctor/GP about any other questions you may have.

Everyone can carry on reading this information sheet. Thank you!

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 show this.
- You can change your mind at any time without saying why.

If you agree to take part in the study, you will be given a copy of this form to keep after you sign it and so will your parents/guardian. Please ask us if you want to chat about any information in this leaflet.

What information will we get from you?

The study will collect information about you, your progress after your heart transplant, your medical treatment and tests, and how well you are for at least two years.

During your normal medical care there will be some heart tests performed at some hospital visits to look at how your heart is doing. These include:

- An ECG (electrocardiogram): A type of heart tracing that can detect electrical signals produced by your heart. This is done by attaching a number of stickers to your skin. The ECG is a painless test but you might feel some discomfort when the stickers are removed (a bit like removing a sticky plaster).
- An echocardiogram: This jelly scan is used to look at the heart and nearby blood vessels that uses sound waves to create images of the heart to see how it is working.
- An intravascular ultrasound (also called an IVUS): An imaging test that is done when you are in hospital whilst you are asleep (under anaesthetic) which creates images of the heart and blood vessels from the inside of the body to check for narrowing.
- A coronary angiography: A heart test that is normally done in hospital when you are asleep (under anaesthetic) with a dye, which looks at the blood supply of the heart and in particular the blood vessels walls to check for any narrowing that can happen in CAV.

A lot of the information the study collects will come from your normal hospital visits, like when you have to have an echocardiogram, ECG or have a cardiac biopsy or further imaging such as IVUS or angiogram. You will have to make an extra visit to the hospital to be given TR006 and then again for a few visits afterwards to check how you are feeling.

After this study has ended, we may still use your blood and heart samples and also some of the TR006 (that has been made using cells from your own body) for future research of heart conditions. Your name and details will be kept hidden though, so that anyone who is not part of the ATT-Heart Team using the samples will not know it is yours.

Will anyone else know I am doing this?

We will need to use information from you, your medical records and your GP for this research project.

This information will include your name, NHS number, date of birth and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Your parents or the person that looks after you will also be told about the study and will need to agree that you can take part in this study.

GOSH is the sponsor of this research, and is responsible for looking after your information. We will keep all information about your child safe and secure by:

- Making sure that all information used in the study is kept under secure conditions and is strictly confidential.
- Making sure that the information about yourself, your medical condition and your test results will be entered onto electronic databases. All this data will be kept secure and will only be accessed by ATT-Heart study team members, or people who come to check that we are running the study properly.
- Making sure that any medical or research paperwork related to the study is stored securely in filing cabinets in a locked room and is only accessible by the local research team.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that your child took part in the study.

We will keep your study data for the minimum period of 25 years. The study data will then be fully anonymised and securely archived or destroyed.

- You can find out more about how we use your information by:
- Contacting Professor Michael Burch (Email: Michael.Burch@gosh.nhs.uk)
- Contacting the GOSH data protection officer at: your.data@gosh.nhs.uk
- Visiting the GOSH Privacy Policy webpage at: https://www.gosh.nhs.uk/privacy-policy
- Visiting: www.hra.nhs.uk/patientdataandresearch
- Looking at the, "What is GDPR," video explanation at: https://www.youtube.com/watch?v=Vll6V1MgZgY
- Discuss this with the study team if you have any questions.

What happens when the research stops?

Once the study is over, you will continue to regularly see your normal doctor to receive your usual medical care.

What will happen to the results of this study?

The study team will keep in touch with you to tell you about the results of the study.

The results of the study may be presented at scientific meetings and published in medical magazines but no identifiable patient information will be used so no one will know that you have taken part.

How to contact us:
If you want to ask about anything please get in touch with the Study Team at your hospital. **Local Study Team Contact:** **Email:** **Telephone Number:**

Thank you again for reading this information sheet!

Please do feel free to ask <u>any</u> questions you may have about the study.

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YOUNG PERSON PATIENT ASSENT FORM (Guide Age: 11-15 year olds)

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

Chief Investigator: Professor Michael Burch

Participant Study Identification Number:

Please initial box to agree WB

Or cross if you do not agree X

	Please **initial** in the box to agree.
1. I have read the study information sheet.	[ ]
2. Somebody else has explained this study to me.	[ ]
3. I was able to ask questions about the study.	[ ]
4. I have had my questions about the study answered in a way I understand.	[ ]
5. I understand what this study is about.	[ ]
6. I understand that it is OK to stop taking part in this study at any time.	[ ]
7. I am happy to give some of my thymus cells to help make the TR006 that will be used to treat me.	[ ]
8. I am happy to give some blood samples for research.	[ ]
9. I am happy that some of my heart tissue samples will be used for research.	[ ]

10. I am happy that any leftover cells from when the TR006 is made will be used for research.	[ ]
11. I am happy to donate some blood samples and heart tissue samples and any leftover TR006 for other future studies.	[ ]
12. I agree to take part in the ATT-Heart study.	[ ]

If you are happy to take part in ATT-Heart, you can write your name and sign below
If you DO NOT want to take part, DO NOT sign your name.

Name of child	Child Signature	Date

Next section to be completed by the **person taking consent:**

	Please **initial** box to indicate agreement.
I have fully explained the purpose and nature (including benefits and risk) of this study to the participant in a way they can understand. I have invited them all to ask questions on any aspect of the study.	[ ]

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Name of person taking consent.	Signature of person taking consent	Date (DD - MMM - YYYY)

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