Guy's and St Thomas' NHS Foundation Trust | King's College London | London School of Hygiene & Tropical Medicine

Insert hospital logo

A trial to investigate whether a heart pump improves the safety and effectiveness of coronary artery stenting procedures that are predicted to be higher risk

Participant Information Sheet

Scientific Title: Controlled trial of High-risk coronary Intervention with Percutaneous left ventricular unloading (CHIP-BCIS3)

We would like to invite you to take part in a research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please take time to read this information carefully before you decide whether or not to take part. One of our team will go through the information sheet with you and answer any questions you have. Please talk to others about the study if you wish. Ask us if there is anything that is not clear. We understand if you may need some time to think about your decision before deciding whether to take part.

We want to do this study to work out whether using or not using a heart pump helps keep you safe when having an angioplasty and stents. CHIP-BCIS3 is the largest UK study looking at this issue.

There is also a Participant Information Video to accompany this information sheet. You can watch the video by visiting this website:

https://lshtm.cloud.panopto.eu/Panopto/Pages/Viewer.aspx?id=3e58e524-01d8-4daa-96eb-b01b00a05f5c

or by using this QR code:

GLOSSARY

The following glossary contains terms that will be used in this information sheet. Please ask your doctor or the research team to explain any words or information you do not understand.

Angiogram When we put a small tube in the groin or wrist and it is passed to the heart. We can then take pictures of the arteries with X-rays to see if any are narrowed.

Catheter A thin hollow tube inserted into the blood vessels, allowing us to do procedures on the heart.

High-Risk A procedure during which the patient is predicted to be at a higher than average risk of complications.

Heart Pump A catheter with a small pump in the end is put into the left side of the heart through a large blood vessel (usually in the groin). It supports the heart during the stent procedure.

Stent Procedure Used to treat narrowed blood vessels of the heart. A small *catheter* is inserted in the groin or wrist and advanced to the heart. Balloons and stents (small scaffolding device) are used to open up narrowings and improve blood flow to the heart muscle.

Why we think this study is important

People who have blockages in the blood vessels in their heart are often offered a stent procedure. Research has shown us stent procedures are generally safe, prevent future heart problems and can improve people's symptoms. Unfortunately, some people who have stent procedures have a high risk of complications, we call these procedures "high risk". The risk is based on the person's general health, how severe the narrowings are, and the condition of the heart at the time of the procedure.

We are looking for new ways to make these high-risk stent procedures safer. A new heart pump has been developed to support the heart. Recent research has made us think these pumps may improve the safety and effectiveness of these procedures, but the research has been too small or not scientific enough for us to know for certain.

This study will involve 300 people having stent procedures. In order to see if the pump is effective, we need half of the people taking part to have the stent procedure with the pump and half without it. In order to make this a fair comparison, we need to choose

which people receive the pump at random. The decision will not be made by your doctor.

Why have I been invited?

Your angiogram has shown that you have blockages of the blood vessels in your heart and you need a stent procedure. Due to your general health and the severity of your heart disease your doctors feel you may be at a higher risk of complications: this should have been discussed with you already. A heart pump may help you, but it is not clear if it will or not.

Do I have to take part?

It is completely up to you whether you take part. A research nurse may get in touch with you after you have read this information sheet to discuss the study and answer any questions you may have. You will also have the opportunity to discuss the study with your doctor. When all your questions are answered and you feel you understand the study we will ask you if you wish to take part.

If you decide to take part, we will ask you to sign a consent form, this confirms that you have read the information sheet, fully understand what is involved and want to take part. We will give you a copy of the information sheet and the consent form that you have signed to keep. Whatever your decision it will not affect the relationship you have with your doctor or the care we give you. Even if you decide to take part you can change your mind at any time without giving us a reason why. If you do change your mind we will ask if you are happy for the information we have collected to still be used.

What will happen to me if I take part?

If you agree to take part, we will use a computer to decide if your procedure will include a heart pump. We will take some blood and other tests, examine you, ask you questions about your medical history and you will have an ECG (an electrical tracing of the heart). These extra tests are to measure how well your heart functions, the amount of blood we will take is less than a teaspoon. We will also ask you to fill in two health questionnaires which will take around 20 mins. You can ask the nurse for help.

Standard treatment: stent procedure without heart pump

If you are in this group your procedure will happen as it normally would outside of the study. We will give you an injection to numb your skin and put the thin, plastic tube in an artery in your wrist or groin. We will use an X-ray to help position the balloons and stents. Your narrowed heart arteries will be opened up by inflating a balloon, we will then put some stents in the artery to make sure it stays open. Before your stent we will give you some medication to stop clots forming, you will need to keep taking these tablets for some time afterwards: your team will let you know how long. At the end of

your stent procedure the blood vessel is closed using a plug, stitches or by a member of staff pressing on the location of the artery.

Study Treatment: stent procedure with heart pump

If you are in this group your procedure will be the same as standard, but with the addition of the heart pump to support your heart during the procedure. We will inject some numbing liquid into the skin at your groin, and the heart pump is then placed using a thin, plastic, flexible tube. X-rays and/or ultrasound may be used to locate the artery at the level of the groin, in order to insert the pump. Occasionally, the heart pump may be inserted via a different artery, such as the one in your armpit or by your collar bone. The device is then guided, using x-rays, into your heart's main pumping chamber. The pump is then turned on and supports the heart throughout the procedure.

At the end of your stent procedure the pump is usually taken out and the blood vessel is closed using a plug, stitches or by a member of staff pressing on your groin for around 30 mins. Occasionally, if your heart needs more support, the pump will need to stay in place when you go back to the ward. If this happens you will need to stay in bed, usually just overnight, but it can be up to 7 days if it turns out that your heart needs continued support. The decision to keep the pump in place, and any potential risks associated with it, will be discussed with you by your clinical team.

What happens afterwards?

After you are discharged from hospital, you will not have any additional study-related hospital visits. You will be contacted by a member of the research team 90 days and every year after your stent procedure for up to 4 years. You will also be contacted at the end of the study. You will be asked two health questionnaires. We will use your GP and Hospital records to monitor your health over the next 10 years. Please note that the clinical team looking after you will advise you about any clinical visits that are required.

What are the possible risks if I decide to take part?

Everyone in the study will have a stent procedure as part of their normal treatment. The risk and benefits of the stent procedure will be discussed with you by your doctor. The next section only deals with risks related to the heart pump itself. We do not know yet whether the overall risks are higher or lower when using the pump: this is why the research is being done.

When inserting the pump into the heart through the artery, there may be bleeding, damage to the blood vessel or damage to blood cells. This happens in around 1 in 20 cases and can usually be managed relatively easily by your doctors. More serious complications happen in less than 1 in 100 procedures; these include severe bleeding,

damage to the blood vessels which needs surgery, a stroke, damage to the heart or death.

As we need X-rays to help us position the pump taking part in this study would involve an extra radiation dose which can potentially be harmful. Ionising radiation may cause cancer many years or decades after exposure. X-rays are used during routine stent procedures and the additional risk to you, of taking part in the study, is small (approximately only 2% higher). Hence, the chances of radiation induced cancer are the same whether you take part in the study or not. The amount of radiation received in the course of your treatment (the stent procedure and pump insertion) will typically be 46 millisieverts, this is equivalent to 21 years of background radiation, the amount of radiation in the environment that comes from the earth itself and the sun.

Expenses and payment

You will not be paid for taking part.

What are the possible benefits of taking part?

As we do not know whether the pump is helpful we cannot say whether or not there will be a direct benefit to you. The information that we get when people take part in this study may improve the treatment of people living with heart disease in the future.

Who can I contact?

[Insert contact details for Local Research Team]

How can I find out the results?

You will receive a letter telling you the results when the whole study has ended. The results of this study will also be reported in medical journals and/or meetings. When this occurs the identity of individuals taking part is not disclosed.

CHIP Trial Extra Information Sheet

Your data, confidentiality, study information and what to do if something goes wrong

What will happen to any data I give?

Collecting and analysing patient information from medical studies is subject to European and national data protection laws, so strict legal controls apply. The Sponsors (King's College London and Guy's and St Thomas' NHS Foundation Trust) will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that they are responsible for looking after your information and using it properly.

Data will be collected about you in several ways:

1. Directly from you by being asked questions and filling out questionnaires.
2. From the results of tests performed at your hospital.
3. From sections of any of your medical notes.
4. Your NHS number, Community Health Index (CHI) number or Health and Care (H&C) number and date of birth will be collected when you have entered the study. This will be used to collect information about your health status such as hospital episode and mortality data through NHS England and other central UK government bodies.

If you consent to take part in the study, you will be allocated a study number, which will be used instead of your name or other identifiable information to identify you on all subsequent forms. This is a measure taken to protect your confidentiality.

Using the study number only, your data and tests will be sent to the following places:

1. Data collected by the research team in your hospital will be sent to the Clinical Trials Unit at the London School of Hygiene and Tropical Medicine.
2. Copies of your test results, including images of your heart and blood vessels will be sent to researchers external to your hospital for further analyses.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw consent from further study treatment, unless you object, your data and blood samples will remain on file and will be included in the final study analysis. To safeguard your rights, we will use the minimum personally-identifiable information possible.

In line with the regulations, at the end of the study your data will be securely archived for 10 years. Arrangements for confidential destruction will then be made.

Any blood samples taken will be destroyed in keeping with local protocols once analysed and will not be stored.

You can find out more about how we use your information at:
www.kcl.ac.uk/innovation/research/support/ethics/how-does-gdpr-affect-ethics/king's-college-london-statement-on-use-of-personal-data-in-research.aspx

www.guysandstthomas.nhs.uk/research/patients/about.aspx

What if relevant new information becomes available?

A group of doctors will review all available information regularly to ensure that the drug and device treatment given to you is the best and most up to date. Sometimes we get new information about the treatment being studied.

If this happens, your research doctor will tell you and discuss whether you should continue in the study. If you decide not to carry on, your research doctor will make arrangements for your care to continue. If you decide to continue in the study your doctor may ask you to sign an agreement outlining the discussion.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Contact details can be found at the end of this Participant Information Sheet.

If you remain unhappy and wish to complain formally, you can contact the Complaints Department / Patient Advice and Liaison services (PALS) team *(delete as appropriate)* [INSERT LOCAL DETAILS].

In the event that something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against Guy's and St Thomas' NHS Foundation Trust and/or King's College London but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Will my taking part in this study be kept confidential?

If you agree to take part in this study, the records obtained while you are in this study as well as related health records will remain strictly confidential at all times. The information will be held securely on paper and electronically at your treating hospital and the organisation responsible for ensuring that the study is carried out correctly, the Clinical Trials Unit at the London School of Hygiene and Tropical Medicine, under the provisions of the 2018 Data Protection Act.

This hospital will collect information from you and your medical records for this research study in accordance with the Sponsor's instructions. They will keep your name and contact details confidential and will not pass this information to the Sponsor (King's College London), the Clinical Trials Unit at London School of Hygiene and Tropical Medicine or the National Institute for Health Research. The hospital will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

Your NHS number, CHI or H&C number and your date of birth will be shared with NHS England and other central UK government bodies in order to help contact you or provide information about your health status. The information will be shared in accordance with NHS England or other central UK government body guidelines.

Your GP will be informed of your participation in the study.

Your records may also need to be made available to people authorised by the Sponsor (King's College London), and the Clinical Trials Unit at the London School of Hygiene and Tropical Medicine to check the accuracy of the research study. By signing the consent form you agree to this access for the current study and any further research that may be conducted in relation to it, even if you withdraw from the current study.

The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details. When the results are published, your identity will remain confidential.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/). This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from: www.guysandstthomas.nhs.uk/research/patients/use-of-data.aspx (For GSTT) and www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research (for KCL)
- by asking one of the research team (contact details included below)
- by contacting the Data Protection Officer: (For GSTT: Nick Murphy-O'Kane DPO@gstt.nhs.uk; For KCL: Albert Chan info-compliance@kcl.ac.uk)

Who is organising and funding the research?

This study is being funded by National Institute for Health Research (NIHR). The routine costs of your care will be paid by the National Health Service. The NIHR provide clinical research costs to the institution or hospital for tests and procedures needed for this study, which are not considered normal practice. Your study doctor is not paid for participation in this study.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the London – Bloomsbury Research Ethics Committee.

Further information and contact details

Investigator's name: *(please fill in local details)* Phone number: *(please fill in local details)* E-mail address: *(please fill in local details)*

Study Coordinator's name: *(please fill in local details)* Phone number: *(please fill in local details)* E-mail address: *(please fill in local details)*

NHS Trust responsible for your care: *(insert local NHS Trust name)*