A multicentre randomised controlled trial of surgical versus percutaneous revascularisation of ischaemic left ventricular dysfunction in the United Kingdom, with embedded internal pilot and health economic analysis (STICH3-BCIS4)

PARTICIPANT INFORMATION SHEET

You can contact the research team on:
<<Insert Principal Investigator name>>
<<Insert local site contact details>>
<<(including emergency contact number)>>

Summary

- You are being invited to participate in the STICH3-BCIS-4 trial.
- You have been given this information sheet because you have been diagnosed with reduced heart function caused by coronary artery disease.
- The STICH3-BCIS-4 trial is looking at which of two already provided procedures is better for patients with the same diagnoses as you and which is better for the NHS, cost-wise.
- The two procedures are percutaneous angioplasty or coronary artery bypass grafting.
- Participants will be randomly allocated to one of two treatments to determine the type of procedure they will undergo.
- We are inviting 630 participants aged 18 and over in the UK to take part.
- Data from UK patients will be shared with the STICH-3 Consortium, based in Sweden. They will combine data from at least 2,000 participants of similar trials in multiple countries as part of an international research programme. BCIS-4 is the name of the UK arm of the trial.
- We will ask you to answer some questionnaires as part of the follow-up and on 10 occasions after your procedure, this will be for a total of 4 years. You can do this yourself via a smartphone application (App) or a member of the research team will contact you by telephone.
- We do not know for sure if there are any disadvantages to taking part as both procedures are currently the standard of care in the NHS for patients with the same diagnoses as you. A member of the surgical team will discuss all the risks in detail with you.
- There are no guaranteed benefits to you taking part. You may however receive more regular care due to the follow-ups. You will also contribute to the future healthcare of patients.
- The end of the trial will be considered as month 97 (~8 years) when all data is collected from all participants and we can consider that this data is as correct as possible.

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This information sheet will provide you with information about the trial. You do not have to take part. If you do agree to take part, then you are free to withdraw at a later date. You can find information on how to do this later in this information sheet.

Invitation

You are being invited to take part in STICH3-BCIS4 trial because you have been diagnosed with a condition that reduces heart function, known as ischaemic left ventricular dysfunction (iLVSD) ischaemic meaning an insufficient blood supply as a result of an obstruction in a blood vessel, left ventricular referring to the lower chamber of the left side of the heart and dysfunction meaning that it isn't working as it should. Alongside iLVSD, you have also been diagnosed with coronary artery disease (CAD) and your doctor recommends that you receive treatment.

The purpose of this information sheet is for us to seek your permission for you to take part in this trial and for us to describe what investigations and treatments will be carried out during your participation.

To help you decide whether or not to take part, it is important that we explain why the research is being done, what it will involve and what you will need to do. Please take time to read this information sheet carefully and discuss with others if you wish. It is up to you to decide whether or not to take part. If you decide to take part, you may still change your mind at any time during the trial. A decision to withdraw or decline taking part will not affect the medical care you receive.

If there is any part of this information sheet that you do not understand, or require further information about, please contact us and we will be happy to answer any questions you have. Our contact details are on the final page.

What is the purpose of this trial?

In the UK, over 20,000 people per year with reduced heart function (iLVSD) and CAD undergo treatment by either percutaneous angioplasty and stents (PCI) or coronary artery bypass grafting (CABG). CABG is an open-heart operation where healthy blood vessels from inside the chest, leg or arm are used to "bypass" the blockages, like a detour. PCI is a procedure where the blockages are ballooned and then stented with a small wire mesh tube through a small incision in the wrist or groin.

Both CABG and PCI are currently offered to patients with the same diagnoses as you in the NHS. However, we do not yet have enough high-quality evidence to know for sure that the intervention selected as part of your care is the best choice for you. This is mainly because trials done before have only included small numbers of patients with iLVSD and the risks and benefits of the two procedures are likely to be different compared to people without iLVSD. We are therefore doing this trial to be able to understand which procedure is better for patients with the same diagnoses as you and which is better cost-wise for the NHS.

In some people the choice of stents versus CABG is clear. However, many patients will be suitable for either stents or surgery with no clear evidence which is best. It is this second group of people who

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we will be recruiting to the trial. If you decide to take part, you will receive one of the two previously mentioned procedures at random (decided by a computer) and your recovery will be monitored afterwards.

In the UK, this trial will include 630 participants from at least 28 hospitals and will be known as the BCIS-4 trial. Similar trials will also be running in other countries including Sweden, Canada, Australia, New Zealand, Denmark, Germany, USA and The Netherlands. The data collected in all of these trials will be put together and analysed to further decide which procedure is better for patients with reduced heart function as well as coronary artery disease. This element will be known as STICH-3.

Do I have to take part?

No, it is up to you to decide whether or not you want to take part. If you do decide to take part but later change your mind, you are free to withdraw at any time using the contact information provided at the end of this document.

You do not have to give any reason for not taking part or for withdrawing. If you choose to withdraw, we would like to continue collecting information about your health from your medical records and through NHS Digital. If you do not want this to happen, tell us and we will stop. If you lose the ability to decide whether you wish to continue participating and you have not nominated a friend or a relative to make this decision on your behalf (see following section) we will make sure that you are withdrawn from the trial and that no further data is collected from that point.

What will happen to me if I take part?

If you decide you would like to take part and you are satisfied that all your questions about the trial have been answered, a member of the trial team will go through the consent process with you and ask you to sign a consent form either in wet ink (black biro) or electronically. You will be given a copy of the consent form to keep for your records.

If you decide to take part, we would also like to seek consent to contact a relative or a friend so that we can contact them if you become unable or too unwell to speak to the research team, or if you become unable to respond on your own behalf. We will ask you to speak to someone who might be willing to do this. If you are able to identify someone, we will ask you to provide them with the contact details of the research team who will be able to answer any queries and the Personal Consultee Consent to Contact Information Leaflet and the Personal Consultee Information Sheet for their reference . If they would be willing to act on your behalf, if necessary, they should complete and return the Personal Consultee Consent to Contact Form to the research team. In the event that you become unable or too unwell to speak to the research team, or if you become unable to respond on your own behalf whilst the trial is still active, the research team will get in touch with your nominated relative or friend. At this point the research team will ask your relative or friend if they would be happy to answer some questions about you related to the trial. If they are happy to do so, they will

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be asked to sign the Personal Consultee Declaration Form before being asked to provide any information about you.

Once you have provided consent you will be assigned randomly into one of the two groups:

Revascularisation by Percutaneous Angioplasty and Stents (PCI)

OR

Revascularisation by Coronary Artery Bypass Grafting (CABG)

Both of these methods are currently standard of care across hospitals with individuals with the same diagnoses as you, with iLVSD alongside CAD. Revascularisation meaning the restoration of blood flow to parts of your heart when that flow is limited or blocked.

The chance of being allocated to either procedure is 50:50, meaning you will have an equal chance of being placed in either group. This is done to create two groups of patients that are as similar as possible, allowing us to compare the two procedures fairly. Splitting people into treatment groups like this is called a 'randomised controlled trial'.

You and the team of doctors and nurses overseeing your care in hospital will be informed of which group you have been allocated to. Neither you nor the researchers will be able to choose or control what group you will be in. We will also write to your GP, notifying them that you are participating in this trial and of what procedure you have been randomised to receive. We will ask for your consent to do this in the Informed Consent Form.

If you are randomised to the PCI group, a catheter (a thin flexible tube) will be placed to force a passage through the blockages (ballooning) and a small wire mesh tube called a stent will be placed to keep the blood vessels, that have been narrowed by plaque build-up, open in your heart.

If you are allocated to the CABG group, you will have bypass grafts around the blockages, like a detour, using healthy blood vessels from within your chest, leg or arm.

You will be required to attend the hospital twice (including for your procedure) and will be followed up on 10 occasions, once whilst you are still in hospital following your procedure and before you are sent home and then at 9 time points as follows: 3 months after your procedure and then every 6 months until year 4. This will be a total follow-up time, for which you are contacted, of 4 years.

The tests and questionnaires are detailed in the table below along with the estimated length of time each will take. You will be able to enter your own responses for each of the follow-ups without visiting the hospital using the ResearchApp™ of the Healthbit® platform (smartphone application). The research team will provide you with information on how to access this at your first visit and you will receive reminders on your phone each time a follow-up is due. If you are unable to access smartphone technology, please let your research team know and they will be able to contact you by telephone. If you do have access to smartphone technology but would prefer to be contacted by phone to conduct your follow-ups, then please also let your research team know.

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Visit Schedule	Approximate Duration
Screening – Day -90 to 0 The research team will check that you are eligible for the trial, your local Heart Team will confirm it is feasible for you to take part and you will be asked to provide consent (electronic or face to face). If you are female and it is thought you could be pregnant, a pregnancy test will be performed before we ask you to do anything related to the trial. If you are pregnant, you will not be able to take part in the trial as this is an exclusion.	Between 30 and 45 minutes
Baseline Assessment – Day -30 to 0 We will collect demographic data (data about you), medical and cardiac history (including long term conditions and severity of cardiac diseases), review of medications, review of symptoms, we will ask you to complete trial related questionnaires and randomisation will be performed.	Between 1 and 1.5 hours
Day of Surgery – Day 0 You will receive **either** PCI or CABG. There will also be a review of your medications and measurement of how well the procedure has worked.	Between 1 and 6 hours depending on procedure
Post procedure until you are discharged home Review of medications, whether anything else has happened related to your health and 2 trial questionnaires.	20 minutes
All of the below will be performed using either ResearchApp™ of Healthbit® (smartphone app) or over the telephone with the research team. You will not need to visit the hospital	
3 Months after your procedure Review of medications and 4 trial questionnaires	Between 30 and 60 minutes
6 Months and every 6 Months to 4 Years Review of medications and trial questionnaires. At every time point within this range you will be asked to respond to two questionnaires related to your condition. At 6 months, 12 months and then annually you will also be asked to complete 2 additional questionnaires related to quality of life and your access to healthcare. The maximum number of questionnaires you will be required to complete at any one time is 4.	Between 20 and 60 minutes depending on number of questionnaires
After last follow up and until the end of the trial This will not require any involvement from you, but where you are still happy for us to do so, we will collect data from your healthcare provider related to your health status (NHS Digital or equivalent). We will not collect more data than we need to.	N/A

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Linking your personal data

It is very important to understand the long-term health condition of patients with the same diagnoses as you involved with the trial to find out if the treatments we are giving are effective. Therefore, we may want to perform 'data linkage' at some point in the future. This means accessing routinely stored health data about you using NHS record linkage services (or equivalents in Scotland, Wales and Northern Ireland). This will allow us to access health information about you, with your permission. In order to do this, we will ask for your consent to provide these services with some of your personal details (including NHS number or equivalent, date of birth and sex). With this information, the NHS record linkage services (or equivalents) will be able to provide us with simple health information about you (such as medical events and hospital admissions) beyond the direct follow-up period (4 years). This means if you are recruited earlier on in the trial, we will collect more data via this route compared to someone who is recruited later on, because there will be longer left until the end of the recruitment and follow up phases. Your personal information will be provided to these services in strict confidence, will be kept securely, and will not be released to any third parties.

Will I receive any payment for participating in the trial?

No, we are unable to pay you for taking part in the trial. You will be able to provide consent electronically if you prefer and you can access the necessary technology. The research team will try to book your baseline assessment and consent visit (if you would prefer to provide consent in person) at a time when you would be visiting the hospital anyway. It may be that you are already in hospital at the time the research team speak to you. We therefore don't expect your travel expenses to be different than those from your routine hospital visits.

What are the possible benefits of taking part?

There are no guaranteed direct benefits to taking part in the trial. Your condition may remain the same, improve, or worsen. However, given that the research team will be in touch with you regularly to find out how your health is following your procedure, you might receive more regular care compared to someone who has not taken part.

All participants taking part in this trial will be helping to make a significant contribution to research. The results of this trial may lead to better treatment for other patients with coexisting CAD and heart failure in the future.

What are the possible disadvantages and risks of taking part?

Both PCI and CABG are standard of care and taking part in this trial presents no added risk to that which you would experience if you were being treated outside of the trial. As we do not know whether it is better for patients with your conditions to receive PCI or CABG, we do not know for sure

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if there are any disadvantages. CABG is a major undertaking, carries higher risk, requires a longer recovery period, and may not be suitable for everyone. However, in people without iLVSD, CABG reduces the rate of death and repeat heart attacks in the long- term compared to stenting.

In contrast, cardiac stenting is minimally invasive, and a simpler procedure with fewer risks, and a quicker recovery. However, the long-term results of stents are often not as good and over time it may become necessary to repeat the procedure.

As the intervention is not a research procedure, a member of the surgical team will discuss all the risks with you in detail when they go over the procedure with you.

What if new information becomes available?

As part of the trial, we may uncover medical conditions not previously recognised. If this happens, we will assess your condition and manage you accordingly, which may result in referral to other specialist teams or back to your GP for further investigations.

If new information becomes available about the procedures offered in this trial, we will let you know and will ask you to re-consent to the updated information if required. We will also discuss with you whether you wish to continue with the trial and what other options may be available to you.

What if something goes wrong?

If you have a concern about any aspect of this trial, you should ask to speak with a member of the research team who will do their best to answer your questions. If you have concerns about any aspect of the way you have been approached or treated during the course of the trial, you may wish to contact the hospital's Patient Information and Liaison Service (PILS). Contact details can be found below. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. Details can be obtained from the PILS office or the hospital.

It is very unlikely that you would be harmed by taking part in this type of research trial. In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

If you wish to make a complaint, or require advice about taking part in the trial you can contact <insert NHS PILS information>.

How will we use information about you?

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

This information will include your:

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- Initials (held by the University of Leicester, Leicester Clinical Trials Unit)
- NHS/CHI number (or equivalent) (held by your hospital and the University of Leicester, Leicester Clinical Trials Unit)
- Date of birth (held by your hospital and the University of Leicester, Leicester Clinical Trials Unit)
- Name and contact details of you and a friend or relative (if nominated) (held by your hospital)

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 unique code number instead. We will keep all information about you safe and secure. Some of your information will be sent to Sweden. They must follow our rules about keeping your information safe. Once we have finished the trial, 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 you took part in the trial.

Will my participation in this trial be kept confidential?

All information which is collected about you during the trial will be kept strictly confidential. We take confidentiality very seriously.

On the consent form, you can choose whether or not you would like to be informed about the results of the trial. If you agree, we will store your contact details securely, separately from your clinical information and we will only use them for the purposes you have chosen. Your contact details will be destroyed once they have been used for the purpose that you have agreed to. However, if you consent to future research, we will keep your signed informed consent form indefinitely as evidence of your consent and to support any of this potential research.

As we will be using information about you to undertake this trial, the University of Leicester will act as the Data Controller for the UK arm of the trial (BCIS-4). Some of the data we collect about you will feed into a wider Consortium called STICH-3 that is being run by the Gothia Forum for Clinical Trials, Clinical Trials Centre in Sweden (also known as the SWEDEHEART team). For this purpose, the SWEDEHEART team will act as both the Data Processor and the Data Controller. We will only ever send data to the SWEDEHART team that is pseudonymised, which means coded so it will not be possible to identify you.

All pseudonymised research data will be stored for a period of 6 years in the UK and 25 years in Sweden after the trial has finished. These data will then be destroyed. This is in line with the legal requirements of each country.

Your data may be accessed by authorised individuals from the research team, Sponsor (the University of Leicester) and its Clinical Trials Unit (Leicester Clinical Trials Unit, LCTU), participating NHS Trusts, regulatory authorities and the host NHS organisation, for monitoring and audit purposes. Your data will also be accessed by the collaborating partners of this trial including the SWEDEHEART team.

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The data that we collect about you will be entered into a secure, password-protected database called Healthbit® and will be accessible only to essential trial personnel. You will be assigned a unique identification number when you join the trial which will be in place of any identifiable information, such as your name.

All data collected as part of this trial will be treated with the strictest confidence and in accordance with legal and ethical requirements for data storage. All data we collect is stored in securely locked filing cabinets and in password-protected databases.

You should be aware that we have a professional and ethical duty to act on concerns for your safety and welfare. If we identify welfare issues, such as deteriorating illness or concerns of abuse, we may need to report these to your GP, your hospital team, or social services. We will tell you if we do this.

What are your choices about how your information is used?

- You can stop being part of the trial at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this trial, you will have the option to take part in future research using your data saved from this trial.

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/
- On the following website: www.le.ac.uk/patient-gdpr-guidance
- By asking one of the research team
- By contacting us via the e-mail address or phone number at the end of this sheet
- By contacting the University's Data Protection Officer, University of Leicester, University Road, Leicester, LE1 7RH please email dpo@leicester.ac.uk

What will happen to the results of this trial?

A copy of the findings of this trial will be offered to you through a newsletter and/or dissemination of a webpage link should you agree to this on the consent form.

The results will also be published in academic journals and presented at conferences and other meetings, as well as used in discussion with policymakers regarding the current and future treatment options for people with your condition. It is important to note that it will not be possible to identify you in any of the information included in these publications.

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What should I do if I want to take part in this trial?

If you are interested in taking part, please let one of the research team know, either at your visit / hospital stay or via the contact information at the end of this information sheet.

You will be asked to complete an Informed Consent Form and to opt-in to a variety of research options by placing your initials within the Yes or No boxes. This will confirm you understand how your data will be processed, protected and reviewed for research purposes.

Who is organising and funding this research?

This research is funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme and sponsored by the University of Leicester. The Leicester Clinical Trials Unit is overseeing the organisation and management of the trial.

Who has reviewed this research trial?

All research that involves NHS patients or staff, information from NHS medical records or uses NHS premises or facilities must be reviewed by an NHS Research Ethics Committee before it goes ahead.

This research was granted a favourable opinion by the XXX Research Ethics Committee, favourable opinion means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information on which to make an informed decision.

The trial has also been reviewed by the University of Leicester, as well as an independent Patient Advisory Group which comprises members of the public.

Thank you for taking the time to read this information and consider taking part in this research.

Please keep a copy of this Participant Information Sheet.

Contact Details

Consultant/Surgeon:	***Insert name***	**Research Nurse:**	***Insert name***
Tel:	***0000 000 0000***	**Tel:**	***0000 000 0000***
E-mail:	***Insert email address***	**E-mail:**	***Insert email address***

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