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REVIVED

REVASCULARISATION FOR
ISCHAEMIC
VENTRICULAR
DYSFUNCTION

# Patient Information Sheet

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**Study Title: REVascularisation for Ischaemic VEntricular Dysfunction (REVIVED-BCIS2)**

**A Randomised Controlled Clinical Trial**

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 participate in this study. 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.

The purpose of the REVIVED-BCIS2 study is to assess whether treatment of heart arteries by angioplasty and stenting (*PCI*) in combination with Optimal Medical Therapy (OMT) can improve heart muscle function, quality of life and life expectancy of patients compared to OMT alone. This will be the largest and most scientific study to date comparing OMT and *PCI* with OMT alone in patients such as you.

## GLOSSARY

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

**Angiogram Procedure** Where a small tube is inserted into the groin or wrist and is passed to the heart. Pictures are then taken of the heart arteries by X-ray to show any narrowings.

**Biventricular pacemaker** A treatment for *heart failure* using a pacemaker or *ICD* to stimulate the right and left side of the heart causing the lower chambers of the heart (ventricles) to beat at the same time.

**Coronary Artery Bypass Graft (CABG) Surgery** To improve the blood flow to the heart. Arteries or veins from elsewhere in the body are graphed to the coronary arteries to bypass the narrowings and improve the blood supply to the heart muscle.

**Echocardiogram** A test that uses sound waves to visualise the beating of the heart.

**Electrocardiogram (ECG)** Records the electric activity of your heart.

**Heart Failure** A health condition in which the heart has a reduced ability to pump blood to the body.

**Implantable Cardioverter Defibrillator (ICD)** An ICD is made up of a battery and a small computer. All of the components of the ICD are sealed inside a metal can about the size of a small pager. Additionally, an ICD monitors your heart's rhythm and can deliver therapy such as small electrical impulses and/or shocks through the lead system depending on the need of your heart. If a fast heart rhythm is detected, then these small

electrical impulses and/or shocks can slow down your heart. An ICD is placed under the skin in the upper chest area during an operation.

**Magnetic resonance imaging (MRI)** A test that uses radio waves and magnets to produce a detailed image of the heart.

**Percutaneous Coronary Intervention (PCI) Procedure** is used to treat the narrowed coronary arteries of the heart. A small tube is inserted in the groin or wrist and advanced to the heart. Small balloons and stents (small scaffolding device) are used to open up narrowings and improve blood flow to the heart muscle.

**Stress echocardiogram** An *echocardiogram* that is done during or just after a period of exercise. If you cannot exercise, then you may have been given medication to increase your heart rate like if you were exercising.

## What is the purpose of the study? (The scientific question being asked)

Patients with *heart failure* are traditionally treated with a combination of tablets and (in some cases) by insertion of a special pacemaker. Together these treatments are called Optimal Medical Therapy (OMT). In patients who have *heart failure* as well as narrowed heart arteries, several recent studies have suggested that treatment of the narrowed arteries (by *PCI* or *CABG*) may improve heart muscle pumping strength and *heart failure* symptoms. However, most of these studies have been too small or have not been scientific enough to allow widespread use of *PCI* or *CABG* as a treatment for *heart failure*.

## Why have I been invited?

Your *angiogram* has shown that you have narrowing of your coronary arteries. Your *echocardiogram* has also shown that your heart does not pump effectively. Your *MRI* or *stress echocardiogram* has shown that there may be a benefit to the pumping strength by improving blood supply to your heart muscle. Your doctors have decided that they would be happy for you to be treated either by *PCI (*in combination with OMT*)* or by OMT alone. Currently patients with your condition in this hospital are being invited to participate in the REVIVED-BCIS2 study.

## What will happen to me if I take part?

Those who agree to participate in the study will be randomly assigned to receive **OMT alone** or ***PCI* as well as OMT**. This means that the choice of treatment will be selected at random (via a computer programme) rather than by your doctor. The process of randomisation makes the study scientifically strong and allows the findings to be used to guide treatment of patients in the future.

If you agree to the study, some blood will be taken in addition to routine tests. The extra tests are to measure changes in your heart function. The amount of extra blood taken will be less than 5ml (about a teaspoon).

### Standard Treatment: Optimal Medical Therapy (OMT)

OMT includes the best medication (tablets) that are currently available for *heart failure*, at doses that are individually tailored to you. This strategy often involves insertion of a special type of pacemaker (called a *biventricular pacemaker*, which may also function as an *Implantable Cardioverter Defibrillator or ICD*), which helps the muscle pump more efficiently and can protect you from the effects of potential abnormal heart rhythms.

These are standard, established treatments that should be considered for all patients with your condition, regardless of this study.

### Study Treatment: Percutaneous Coronary Intervention (PCI)

All patients assigned to this group will have OMT, as above. In addition they will undergo a procedure to reopen the narrowed heart arteries to improve the blood supply to the heart muscle. This procedure is called *Percutaneous Coronary Intervention (PCI)*, this is also known as angioplasty and stenting and is currently performed routinely (approximately 75,000 procedures per year in the UK) for treatment of angina. The procedure is performed under local anaesthetic via an artery at the top of the leg or the wrist, under X-ray guidance. The narrowed heart arteries are reopened by inflation of a balloon and one or more stents are then inserted into this part of the artery to ensure that it remains open. During *PCI*, pressure measurements are sometimes taken from within the artery, while a drug called Adenosine is infused via a cannula (drip) in a vein. This is often accompanied by sensations of chest tightness and of your heart beating fast, which are short lived and stop very shortly after the drip is stopped. If you find this intolerable at any stage, the drip will be stopped immediately. Before *PCI*, you will be required to take tablets to prevent blood clots from forming within the stents (a combination of Aspirin and Clopidogrel are the most common treatment used). These tablets are usually continued for at least one month after *PCI*, often for a year and sometimes longer. Your cardiologist will advise on the precise duration. Patients are discharged the same day or one day after *PCI*.

Prior to the *PCI* procedure(s) or before optimising your medications you will undergo some routine hospital tests and examinations. This will include questions regarding your medical history, a physical examination, an ECG and some hospital blood tests. These blood tests may be in addition to routine care. The extra tests are to measure changes in your heart function. The amount of extra blood taken will be less than 5ml (about a teaspoon). You will be asked to complete two health questionnaires that should take about 20 minutes to complete. The nurse will help with this if needed.

## Follow-up

You will be followed up at 6 months, 1 year and then yearly for up to 5 years after being included in the study. At 6 months, 1 year and 2 years after consenting to the trial you will be asked to come back to have an appointment with a member of the research team. At this point you will undergo some hospital tests as you did at the beginning of the study. This will include questions regarding your medical history, a physical examination, health questionnaires and some blood tests. If you have a special

*ICD* device this will also be checked at these times. You will also undergo an *echocardiogram* at 6 months and 1 year. These follow-up appointments should not take more than about two hours. After this, you will be contacted yearly for up to 5 years by telephone to follow your progress. You will again be asked to complete a health questionnaire that we can either send you in the post or complete over the telephone.

A summary of the additional study follow-up that is above normal hospital care is provided in the table on the next page:

| Time | Procedure |
|---|---|
| Study consent | Allocated to *PCI* or Optimal Medical Therapy |
| 6 months | Clinic visit including Echocardiogram and *ICD* check |
| 1 year | Clinic visit including Echocardiogram and *ICD* check |
| 2 year | Clinic visit including *ICD* check |
| Yearly | Phone call and questionnaire |

## Do I have to take part?

Your participation in this study is completely voluntary. Please take the time to read this information sheet. You may be contacted by the research nurse to discuss the study and to ask any questions you may have, and you will have an opportunity to discuss the study further with your doctor. Once you are happy that you fully understand the study, you will be asked if you wish to participate.

If you decide to participate in this study, you will be asked to sign a consent form. By signing this consent form you will confirm that you have read the information sheet and fully understand what is involved, that you will participate in this study, and that you will follow the study requirements. You will receive a copy of the information sheet and the signed consent form to keep. Your decision whether or not to take part will not change your current or future relationship with your doctor or the hospital. If you decide to participate in the study, you are free to withdraw from the study at any time, without having to give a reason. Sometimes it is possible that you do not want to continue in the study but you are happy for the information already collected to still be used. You will be asked whether you are happy for this if at any time you decide you do not want to continue in the study.

## Expenses and payment

You will not be paid for participating in the study, however expenses for your travel will be covered for the extra clinic visits (public transport and/or parking charges).

## What are the possible disadvantages and risks of taking part?

Given that all patients with *heart failure* are given *OMT*, the additional risk to participating in the study relates to the *PCI* procedure.

On average, the risk of major complications (including damage to an artery, heart attack, stroke or death) during or shortly after *PCI* is approximately 1% (1 in 100). Specifically the risk of death or of needing to proceed to emergency heart bypass surgery is 1 in 500.

Of the patients who undergo a successful *PCI* procedure, 5-10% can develop gradual re-narrowing within the stent, which may require treatment by a second *PCI* procedure or *CABG* surgery at a later date. Rarely, sudden blockage of stents can occur due to formation of a blood clot within the stent but you will be given medication that prevents clots from forming (as mentioned above) which will reduce this risk significantly.

*PCI* procedures involve exposure to ionising radiation in the form of X-rays, which can potentially be harmful. Participation in this study would involve an extra radiation dose of on average 18.3 mSv for those patients allocated to the *PCI* group. This would be the equivalent of 8 years of background radiation. Background radiation is the amount of naturally occurring radiation in the environment coming from the earth itself and the sun's rays. The maximum possible radiation dose that would be received through taking part in the study could be up to 47.2 mSv, which is equivalent to 21 years of normal background radiation.

## What are the possible benefits of taking part?

As the benefit of treating narrowed arteries has not been clearly established yet, you should assume that there would be no direct benefit to you. However, information we obtain from your participation in this study is likely to improve treatment of patients with heart failure in the future.

## 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 Sponsor (King's College London) 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 will be collected when you have entered the study. This will be used to collect information about your health status through NHS Digital.

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 London School of Hygiene and Tropical Medicine.
2. Copies of your *echocardiograms* (echos) and a copy of either your *MRI* or *stress echocardiogram* report will be sent to researchers at St Thomas' Hospital in London.
3. Copies of your *angiogram* will be sent to researchers at Golden Jubilee National Hospital in Glasgow.

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 a minimum of 20 years. Arrangements for confidential destruction will then be made.

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

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

## What if relevant new information becomes available?

A medical therapy committee 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 information sheet.

If you remain unhappy, you may be able to make a formal complaint through the NHS complaints procedure. The contact telephone number for the complaints department can be found at the end of this information sheet.

This trial is co-sponsored by King's College London and Guy's and St Thomas' NHS Foundation Trust. The sponsors will at all times maintain adequate insurance in relation

to the study independently. King's College London, through its own professional indemnity (Clinical Trials) and no fault compensation, and the Trust have a duty of care to patients via NHS indemnity cover, in respect of any claims arising as a result of clinical negligence by its employees, brought by or on behalf of a study patient.

## Will my taking part in this study be kept confidential?

If you consent 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) or the Clinical Trials Unit at the London School of Hygiene and Tropical Medicine. This 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 will be shared with NHS Digital in order to help contact you or provide information about your health status. The information will be shared in accordance with NHS Digital 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.

## What will happen to the results of the research study?

The results of this study will be reported in medical journals and/or in medical meetings. When this occurs the identification of individuals taking part is not disclosed.

## Who is organising and funding the research?

This study is being funded by The National Institute of Health Research Health Technology Assessment Programme (NIHR HTA). The routine costs of your care will be billed to your insurance company or National Health Service as normal. This study is being run by King's College London, who will 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 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 Westminster Research Ethics Committee.

## Further information and contact details

Investigator's name: *(please fill in local details)*

Phone number: *(please fill in local details)*

Study Coordinator's name: *(please fill in local details)*

Phone number: *(please fill in local details)*

Complaints Department / Patient Advice and Liaison services (PALS) *(delete as appropriate)* telephone number: *(insert local number)*

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