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Participant information sheet

Study title: REPRIEVED trial – a study to find out if heart stents can improve quality of life for people with heart failure with preserved ejection fraction (HFpEF) and heart artery disease.

Chief Investigator: Dr Matthew Ryan, King's College London

Scientific title: REvascularisation for heart failure with PReserved ejection fraction and Ischaemia: EValuation of Efficacy and mechanistic Description (REPRIEVED)

Study contact details

Investigator's name: [please insert local details]
Phone number: [please insert local details]
E-mail address: [please insert local details]

Study Coordinator's name: [please insert local details]
Phone number: [please insert local details]
E-mail address: [please insert local details]

NHS Trust responsible for your care: [insert local NHS Trust name]

We would like to invite you to take part in this research study.

This information sheet explains why the research is being done, and what taking part would involve.

Taking part is entirely your choice. You can say no, or you can join and later change your mind, without giving a reason. This will not affect your usual care.

Please take your time when reading this information sheet. You can ask us as many questions as you wish. You can also speak with people you trust, such as friends, family, carers, or others who support you.

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List of words and their meanings that we use in this information sheet

Here is a list of words and their meanings that we use in this leaflet that may help you. You can also ask your doctor or a member of the research team to explain anything you do not understand.

CT angiogram: A non-invasive scan of the heart that uses X-rays to see if you have heart artery disease.

Coronary angiogram: A procedure where a thin, flexible tube is inserted into your wrist or groin and guided to your heart. X-ray pictures show if your heart arteries are narrowed.

Catheter: The thin, flexible tube used during the coronary angiogram.

HFpEF (Heart Failure with Preserved Ejection Fraction)**:** A condition where your heart muscle becomes stiff. This means the heart fills with less blood and cannot pump as well as it should.

Randomisation: The process where people are randomly allocated by chance to one of the treatment groups. This process makes sure that any differences we see between the groups are due to the treatment itself and not caused by other factors.

Stent procedure: A minimally invasive treatment used to open narrowed or blocked arteries. A stent procedure involves a coronary angiogram, and balloons and stents (small expandable metal tubes) are used to keep narrow blood vessels open, improving blood flow.

Placebo procedure: A procedure that involves a coronary angiogram but does not involve balloons and stents. The use of a placebo is important in this study so we can be sure that stents work.

If any other words are unclear, please ask us.

About this study

Why is this study being done?

HFpEF (heart failure with preserved ejection fraction) is a condition where the heart muscle stiffens and can't pump blood properly. People living with this condition often also have heart artery disease, also called coronary artery disease, where the blood vessels that supply the heart are narrowed or blocked. We do not yet know whether opening these arteries with stents improves symptoms or quality of life with HFpEF.

The REPRIEVED trial aims to answer this question.

To do this, we will compare two groups of people with HFpEF and heart artery disease:

- One group will have a stent procedure.
- One group will have a placebo procedure that feels the same as a stent procedure but does not include a stent.

Participants, their doctors, and the research team doing check-ups will not know which group participants are in until the end of the study. This helps us understand the true effect of stents, so we can be confident about whether they help people with this condition. 350 people across the UK will take part, and we will monitor their health over six months to see if and how quality of life changes.

By running this clinical trial, we hope to improve treatments for HFpEF, and the lives of people living with this condition.

What is a clinical trial?

A clinical trial is a type of research study that helps us find out whether a treatment works and how safe it is. We do clinical trials when there is more than one treatment option available for patients with a condition or disease, and we don't know which one is best.

To make the results fair and trustworthy:

- People are randomly allocated to one of the treatment groups; this process is called 'randomisation'.
- In this study, there is a 50:50 chance of receiving the stent procedure or the placebo procedure.
- Neither you nor your clinical team can decide which treatment you will receive.

Randomisation helps us understand the true impact of the treatment being tested. This process makes sure that any differences we see between the groups are due to the treatment itself, and not caused by other factors such as age, other health conditions, or how severe someone's symptoms are.

REPRIEVED is a randomised clinical trial that aims to find out if heart stents can improve quality of life for people living with heart failure with preserved ejection fraction (HFpEF) and heart artery disease.

Why have I been invited to take part?

Your doctor believes you have HFpEF and either have, or may have, heart artery disease. A stent procedure may help you, but we currently do not know for certain.

Do I have to take part?

No, taking part is entirely your choice. Your usual care will not be affected if you decide not to take part.

What if I change my mind about taking part?

You are free to change your mind about taking part at any time, and do not have to give a reason. If you decide you no longer want to take part, we will ask whether we may keep the information already collected, as this helps us understand the trial results.

Will I be paid for taking part?

Taking part in the trial is entirely voluntary, however you will be offered:

- A £10 gift voucher after your first appointment as a thank you for participating
- Reimbursement for travel
- Support for carers or carer relief costs to enable you to attend trial appointments

There is no additional payment for taking part.

How can I find out about the results?

If you take part in the trial, we will send you a summary of the results in a letter once the trial is complete. You will also be invited to an online meeting where you can hear about the findings and ask questions.

What does the study involve?

What will happen if I take part?

Consent

We will ask you to sign a consent form. This confirms that you have read the participant information sheet, fully understand what will happen and want to take part in the study.

You should keep a copy of the information sheet and signed consent form. Whatever your decision it will not affect the relationship you have with your doctor, and you will still receive the best standard care.

Eligibility

We will ask you to come to the hospital where we will ask you questions, look at your medical history and let you know if you can take part. If you agree to take part and your doctors think you might have coronary artery disease, you may need to have a scan. This will confirm whether you have coronary artery disease or not.

Tests

We will ask you to give a blood sample (around a teaspoonful), examine you and ask you questions about your medical history. You will have an ECG (electrical tracing of the heart). These extra tests are used to measure how well your heart functions.

Survey

We will ask you to fill in a health questionnaire which will take around 10 mins. You can ask the doctor or nurse for help at any time. We will also look at and maybe adjust your heart medication to try to get it as good as possible for your heart condition.

Treatment

You will then come to the hospital on another day for the procedure, to have either treatment with a stent or the placebo procedure without a stent. We will use a computer to decide which treatment you receive on the day.

If you are randomised to the stent procedure group:

1. Before your stent procedure, we will give you medication to stop blood clots forming.
2. You will receive a local anaesthetic by injection to numb your skin and sedative medication to help you relax.
3. You will receive headphones so you won't hear conversations between staff whilst we do the procedure.
4. A doctor will insert a catheter (thin tube) into your wrist or groin. Most procedures use the wrist, but around 1 in 30 procedures put the tube through the groin.
5. A balloon will be used to open the narrowed artery, and one or more stents will be placed to keep it open.
   An X-ray will be used to help the doctor position the balloon and stents effectively.
6. At the end of your stent procedure the catheter is removed, and the wrist or groin is closed with a wristband, a plug, or gentle pressure.
7. Most people go home from hospital the same day.

8. After your stent procedure, we will give you tablets to stop blood clots forming. You will need to keep taking these tablets for up to 6 months after your procedure: your doctor will let you know how long.

If you are randomised to the placebo procedure group:

1. You will receive the anaesthetic, sedation, and headphones in the same way as for the stent procedure.
2. A doctor will insert a catheter (thin tube) into your wrist or groin. Most procedures use the wrist, but around 1 in 30 procedures put the tube through the groin.
3. No balloons or stents will be used.
4. At the end of your placebo procedure the catheter is removed, and the wrist or groin is closed with a wristband, a plug, or gentle pressure, in the same way as for the stent procedure.
5. Most people go home from hospital the same day.
6. After your placebo procedure, we will give you placebo tablets. These tablets will look exactly like the tablets taken to stop clots forming but do not contain any active ingredients. You will need to keep taking these tablets for up to 6 months after the procedure.

What happens afterwards?

After you are discharged from hospital, you will be contacted by a member of the research team at 3 months and 6 months after your procedure:

3-month visit

- A researcher will contact you by phone or in-person
- You will be asked to complete a short health questionnaire
- Your doctor may adjust your heart medication if needed
- Neither you nor your doctor will know if you have had stents during this time

6-month visit

You will be invited to the hospital for:

- A short health questionnaire
- A scan of the heart (echocardiogram)
- A blood test
- An ECG (heart tracing) to measure any changes in the heart

At this point you will be told whether you received the stent procedure or the placebo procedure. If you did not have a stent, and you and your clinical team feel it is appropriate, you will be offered one. The clinical team looking after you will let you know of any further clinical visits that are required.

Risks and benefits of participation

What are the possible risks?

Every medical procedure has risks, but serious complications are rare. The risks have been carefully reviewed by people living with HFpEF, doctors, independent experts, the research team, the NIHR who fund the research, and an independent ethics committee. Each of these groups have agreed that the overall risks of study participation are worth the potential benefit of finding a new treatment for people living with HFpEF. However, it is very important that you understand and consider these risks before deciding to take part.

People that are interested in taking part in the study may be asked to have a non-invasive scan (CT angiogram), to see if they have coronary artery disease and if they are eligible to take part in the trial. Eligible participants will then have a coronary angiogram, and you may have a stent procedure depending on the treatment group you are allocated to. All these procedures can be extra to those that you would have if you did not take part in this study.

Risks from scans and imaging

Angiograms and stent procedures use ionising radiation to form images of your body and provide treatment. Ionising radiation may cause cancer many years or decades after the exposure. In patients with your current clinical condition, the chance of this happening to you is extremely small.

Risks from the angiogram or pressure-wire study procedure (all participants)

A coronary angiogram can involve a special wire called a pressure-wire study. This procedure involves putting a thin tube (catheter) through the arm or groin to take pictures of the coronary arteries and measure how well they function. A dye (called contrast) is injected during the procedure. The procedure is in regular use to assess patients with angina or heart attacks across the National Health Service (NHS). It is performed by a specially trained heart doctor (cardiologist) called an interventional cardiologist. It is done using local anaesthetic and with medication to make people relax.

Overall, the risk of a major complication from an angiogram and pressure-wire test is around 1 in 400 procedures, meaning that 99.75% of people do not experience a major complication.

The specific risks include:

- Minor bleeding (1 in 50 procedures)
- Major bleeding (1 in 500 procedures)
- Bleeding around the heart (1 in 2,000 procedures)
- Damage to the blood vessels (1 in 1,000 procedures)
- Heart attack (1 in 1,000 procedures)
- Stroke (1 in 2,000 procedures)
- Allergic reaction to contrast dye (1 in 1,000 procedures)
- Kidney damage from contrast dye (1 in 2,000 procedures)

- Death from a planned procedure like this (1 in 10,000 procedures)

Risks from having a stent procedure (stent group only)

People allocated to the stent group will have stents placed within their coronary arteries. Balloons are used to stretch open the narrowed artery, and stents are used to hold them open. The risks of these procedures are the same as for the angiogram but occur slightly more often as the procedure is more complex.

Overall, the risk of a major complication is around 1 in 200 procedures, meaning that 99.5% of people do not experience a major complication.

The specific increased risks include:

- Heart attacks (1 in 500 procedures)
- Stroke (1 in 1,000 procedures)
- Kidney damage (1 in 500 procedures)
- Death (1 in 2,000 procedures)

Risk from medication to prevent blood clotting

After the procedure, you will receive some tablets.

Participants who receive stents will be prescribed aspirin and clopidogrel. Aspirin is used to treat coronary artery disease, and clopidogrel is used to stop blood clots from forming inside the stents for 12 months. These medications are routinely given to people who have stents inserted for heart attacks or angina. Taking these medications together increases the risk of bleeding. Most people only notice that they bruise more easily. The risk of major bleeding from taking aspirin and clopidogrel, as opposed to aspirin alone, is around 1 in 100 over 12 months. There is no increased risk of life-threatening bleeding.

Participants who do not receive stents (the placebo group) will not take clopidogrel. Instead they will receive a placebo tablet with no risk.

What happens if something goes wrong?

If you have concerns about any aspect of this study, please speak to the research team first, they will do their best to help. Their contact details can be found on the first page of this participant information sheet.

If you are still concerned or unhappy, you can contact your local Patient Advice and Liaison Services (PALS) team / Complaints Department (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 NHS complaints mechanisms will still be available to you (if appropriate).

What are the possible benefits of taking part?

We cannot say whether you will personally benefit, as the purpose of the trial is to find out whether stents help people with HFpEF.

However, by taking part, you will:

- Have regular contact with specialist doctors and cardiac research nurses
- Contribute to research that may improve treatment for future patients
- Help us understand which people with HFpEF benefit most from stents

What if relevant new information becomes available?

A group of doctors will review all available information regularly to ensure that the drug and 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 together you will decide whether you should stay 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.

Who is involved with the study?

Who is running and funding the study?

This study is run by:

- London School of Hygiene & Tropical Medicine Clinical Trials Unit
- King's College London
- Guy's and St Thomas' NHS Foundation Trust

The study is funded by the National Institute for Health and Care Research (NIHR). The routine costs of your care will be paid by the NHS. 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?

This trial has been developed with input from:

- People living with heart failure
- Pumping Marvellous, a patient-led charity for people with heart failure
- The British Society for Heart Failure
- The research team, which includes doctors, researchers, patients and members of the public

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your rights and interests. This study has been reviewed and approved by the London Riverside Research Ethics Committee (Reference 25/LO/0277).

Data privacy, confidentiality and further study information

How your information will be used and kept safe

We will need to use information from you, your GP, and your medical records for this research project to run this study safely. This includes your name, NHS number (CHI number in Scotland or H&C number in Northern Ireland), postcode, contact details, and date of birth.

Only people who need to know who you are will have access to this information. Everyone else will see only a code number, not your name or any other personal data.

King's College London and Guy's and St Thomas' NHS Foundation Trust are the co-sponsors of this research. They are responsible for looking after your information. We will keep all information about you safe and secure. Your data will not be shared outside the UK.

We will use your NHS number (CHI number or H&C number), date of birth and postcode to help us find your health records held with NHS England and other central UK government bodies that hold health data, so that we can assess long-term health outcomes. Your personal information will be kept in a safe place separate to the study information and will be deleted after use. We will keep your data for a maximum for 5 years after the end of the study. We anticipate this will take place by the end of 2034.

Once we have finished the study, we will keep some of the data so we can check the results. Some of your health information will be sent to King's College London after the study is complete to support future research. This information will be pseudonymised. This means that anything that could identify you, such as your name and other identifiable information will be removed and replaced with a code number. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data archived for a maximum of 10 years after the trial finishes. After this period, the study data will be securely destroyed.

Your choices about how your information is used

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study or lose capacity during the study, we would like to continue collecting information about your health from your hospital, medical records or GP. Your data will remain on file and will be included in the final study analysis. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means you cannot see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

- If you agree to take part in this study, you will also have the option to allow the research team (within the sponsoring organisation(s)) to securely store your contact details and agree to be contacted about other ethically approved research studies. You will only be contacted by a member of this research team to ask if you want to take part in another research study. You might then be asked if we can give your contact details to another research team within Guy's and St Thomas' NHS Foundation Trust or King's College London. Agreeing to be contacted does not commit you to agreeing to take part in further studies.

Will my taking part in this study be kept confidential?

If you agree to take part in this study, any information collected about you, both during the study and from your health records, will be kept strictly confidential. Your information will be stored securely, both on paper and electronically, at your treating hospital and at the Clinical Trials Unit at the London School of Hygiene and Tropical Medicine (LSHTM), which helps makes sure the study is run correctly. All information will be managed in line with the 2018 Data Protection Act and UK General Data Protection Regulation (GDPR).

Your hospital will collect information from you and from your medical records as needed for the study, following the Sponsor's instructions. They will keep your name and contact details confidential. The Clinical Trials Unit at London School of Hygiene and Tropical Medicine will look at your consent form to check that it is completed properly, and will see your name and contact details. These personal details will not be shared with King's College London and Guy's and St Thomas' NHS Foundation Trust (the co-sponsors), or the National Institute for Health Research.

Your hospital team will use your contact details only to get in touch with you about the study, record information relevant to your care, and help ensure the quality of the research.

We will write to your GP to let them know that you are taking part, unless you ask us not to. This helps ensure that anyone involved in your care has the information they may need.

Your study records may be reviewed by authorised staff from the study Sponsors (King's College London and Guy's and St Thomas' NHS Foundation Trust), and the Clinical Trials Unit at the London School of Hygiene and Tropical Medicine. This may be needed to check that the study is being carried out accurately and safely. When the results of the study are published, they will be written in a way that means no one will be able to identify you.

What will happen to samples I give?

Any blood samples we take for the study will be tested in the hospital laboratory in the same way as your usual clinical tests. Once the results have been received and checked, the samples will be safely destroyed. No blood or other tissue samples will be stored or used for any future research as part of this study.

How can I find out more about how my information is used?

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

- Visiting the Health Research Authority website at: www.hra.nhs.uk/information-about-patients/
- Visiting the Guy's and St Thomas' website at: www.guysandstthomas.nhs.uk/research/patients/use-of-data.aspx (for GSTT) and www.kcl.ac.uk/research/research-environment/rgei/research-ethics/use-of-personal-data-in-research (for KCL)
- Asking one of the research team (contact details can be found below)
- Contacting the Data Protection Officer: (For GSTT: Nick Murphy-O'Kane DPO@gstt.nhs.uk; For KCL: Olenka Cogias info-compliance@kcl.ac.uk)

Thank you for reading this participant information sheet. Please keep a copy for your records.