The British Heart Foundation older patients with non-ST SEgmeNt elevatIOn MyocaRdial Infarction Randomised Interventional TreAtment Trial (The BHF SENIOR-RITA Trial)

Participant Information Sheet & Participant Consent Form

Study Chief Investigator: Dr. Vijay Kunadian, Consultant Interventional Cardiologist, Freeman Hospital/Newcastle University

Site Principal Investigator:

We would like to invite you to take part in a research study called The BHF SENIOR-RITA Trial. Your participation in this study is voluntary. If you do not want to participate in the study, this will not affect your routine care. This information sheet explains why the research is being done and what taking part would involve. Please take time to read the following information carefully and be sure to ask questions about anything that is unclear. Your doctor will answer your questions on the study or any of the information presented here. It is important to know that no study-related tests or procedures will be performed before you sign the consent form to participate in the study. If you decide to take part we will ask you to read and sign a consent form.

What is the background and purpose of the study?

Heart disease, in particular heart artery disease, is the biggest killer in the UK. Over recent years, there have been remarkable improvements in the use of new advanced medications and technologies to treat diseases linked with heart arteries. However, these treatments have primarily been tested in younger patients and we do not have evidence that they also work in older patients. Several previous research studies suggest that older patients (those aged 75 years and over) are less likely to receive the most advanced medications and procedures. This is particularly true for "coronary angioplasty", a procedure that clears blockages in the heart arteries using a balloon and a metal scaffold called a "stent". This is because doctors are

unsure whether in older patients these procedures may cause more harm than the potential benefit seen in younger patients. This is particularly true for individuals who are older and frail.

Frailty in itself might be due to a number of reasons but there are no research studies conducted in frail older patients to guide the correct treatment strategy for a heart attack. It is for this reason that we designed the SENIOR-RITA study. SENIOR-RITA will consist of patients who are aged 75 years and over, presenting with a heart attack.

Why am I being invited to take part?
You are being invited to take part in this research study because you have suffered a heart attack and you are 75 years of age or older.

Do I have to take part?
No, it is entirely up to you to decide whether or not to take part. If you would like to consider helping us by taking part in the study, you should read this information sheet and you will then be asked to sign the consent form. You are free to withdraw from the study at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the care you will receive now or in the future. If you decide not to take part in this study, you will receive normal treatment and it will not be changed in any way.

What will happen to me if I take part?
If you agree to take part, you will be randomly allocated to one of two treatment groups: Invasive treatment group or Conservative treatment group. Random allocation means you have an equal chance of being in either treatment group.

Invasive Treatment: You will undergo the heart artery X-ray test, called coronary angiography. For this procedure, your Cardiologist will insert a small tube in your wrist or groin area using a small puncture in the skin. Tubes will then be advanced through blood vessels to locate your heart arteries, dye will be injected and X-ray pictures of your heart arteries taken. This will show whether you have any blockages in your heart arteries. Your Cardiologist will then discuss with you whether to treat the blockages with medications or coronary angioplasty (inflating a balloon to open the artery and allow blood flow) or refer you for a heart operation (coronary artery bypass graft surgery). The Cardiologist will explain these options to you and together you will decide what is best for you. No matter which group you were in, routine care will be given in the usual way. At some hospitals, if you were randomised to receive an angiogram you may have to be moved to another hospital for that. The person who invited you to take part will be able to tell you if that would apply to you. This is the standard of practice for the management of patients with heart attacks in the UK where angiography/angioplasty facilities are not available at all centres/hospitals and therefore patients will need to be moved to centres where such facilities exist.

Conservative Treatment: You will receive the latest medications to treat patients with heart artery disease. However, you will not undergo a coronary angiogram unless your condition changes and you need to have this procedure. It is important to understand that neither you nor your cardiologist can decide which of the two treatment options you will have. The computer will select your treatment at random. To take part you must be prepared to have

either option. We hope to recruit approximately 1668 patients to the SENIOR-RITA trial from approximately 40 centres all across the UK. We will then be able to evaluate which one of the two treatment groups is best.

During your time in hospital we will gather information on your admission details, medical background, blood tests, heart tracings (ECG), heart scan information, and heart X-ray details (if you are allocated to the invasive group). We will also ask you to fill out some questionnaires to assess your quality of life, frailty health and mental status.

What happens in subsequent follow-ups?
We will follow you up in the clinic at 6 and 12 months, and yearly thereafter for up to 5 years. If you are unable to attend clinic we will contact you by telephone or through postal questionnaires and collect information from your medical notes and GP records. Beyond this, there will be no direct contact with you by the study team but we will use routinely collected health records data via the Office of National Statistics (ONS) and Hospital Episode Statistics (HES) to follow your progress beyond 5 years.

At 6 months and at 1, 2, 3, 4 and 5 years after starting the study we will ask you (or the relative, friend or carer who provides you with support, if you are unable to do so) to complete a brief questionnaire (called EQ5DL-5L quality of life). At 6 months and 1 year after starting the study, we would also like to collect information on how strong you are feeling, whether you are using health and social services and what costs are incurred by you in managing your heart condition; we will collect this information by questionnaires that you can complete at home or by phone.

In addition, we will collect information from your medical or GP records on any important medical events you have experienced and the medications you are taking. We will reassess your mental capacity at 1 year and frailty at 6 months and 1 year. We will measure your frailty status yearly thereafter for 5 years. All this information will be collected at your routine visits where possible, or may be done by phone or post where not feasible to collect this information as part of a routine visit. You will be provided with pre-paid envelopes for return of any required information by post to the study team. You will not have to remember when any of this information is due, as the study team will prompt you at the appropriate times.

What are the possible benefits of taking part?
We hope that SENIOR-RITA study findings will provide us with important insights on the best care of the older patient presenting with heart attacks. This is important not only in the UK but also across the world particularly given the growing number of older patients and those with heart disease.

What are the possible risks or side effects of taking part in the study?
Coronary angiography, coronary angioplasty and coronary artery bypass graft surgery are established treatments for heart disease. The coronary angiography and coronary angioplasty procedures use x-rays, so there is a small risk from the exposure to this radiation. The amount of radiation involved is equivalent to less than three years of exposure to the average natural background radiation in the UK. The risks and benefit of these procedures will be explained during normal routine consent process.

In brief, the angiography and angioplasty procedure-related risk are as follows: in-hospital death (less than 1%), heart attack (less than 1%), stroke (less than 1%), kidney failure (less than 1%) and any bleeding (approximately 2%) of which major bleeding (less than 0.1%).

How long will I be involved in the study?
Your participation in the study will be expected to last up to 5 years. After this, with your permission, we will continue to collect your health-related data via the Office of National Statistics (ONS) and Hospital Episode Statistics (HES) databases.

Will I be paid for participating in the study?
You will not be offered any financial reward for participating in the study. However, we will reimburse any travel costs incurred during the study and therefore we would ask you to keep relevant receipts.

What happens when the research study stops?
At the end of the study, you will continue your usual follow up arrangements with your Cardiology Consultant or GP.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions. Their details are provided at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. (LOCAL SITE COMPLAINT PROCEDURE TO BE ADDED HERE, eg PALS)

Will my taking part in the study be kept confidential?
By agreeing to take part in this study you are consenting to the study staff collecting personal data about you, including the following: your date of birth, your sex, details of your medical condition and your NHS number. In addition, copies of signed consent forms will be sent to the Clinical Trials Unit where they will be checked and then destroyed.

The study data will be entered onto a secure database. Access to this database will be password protected and only available to the research staff. All data stored on the computer will be coded, your name will not appear, but you will be given a unique study number under which all data and test results will be entered. Your records may also be looked at by representatives of regulatory authorities and by authorised people from the Trust to check that the study is being carried out correctly. All individuals involved in this research will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed outside the research site. All the information about your participation in this study will be kept confidential. With your permission we will notify your GP that you are taking part in this study. Participation in the study will also be noted in your hospital records. If you agree we will link your NHS number to your participant data file held in the encrypted data storage data base to allow continued follow up linked to national databases (Office of National Statistics – ONS, and Hospital Episode Statistics - HES).

How will we use information about you?

The Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH) is the sponsor for this study; the study is managed on behalf of the sponsor by the Newcastle Clinical Trials Unit (NCTU) at Newcastle University. We will need to use information from you, your carer (if applicable) and your medical records for this research project.
This information will include:
NHS number
Name
Contact details
Health information

People will use this information to do the research or to check your records to make sure that the research is being done properly.

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

We will keep all information about you safe and secure.

We will write our reports in a way that no-one can work out that you took part in the study.

What are 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, we would like to continue collecting information about your health from your hospital and/or GP and/or central NHS records. 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 that we won't be able to let you see or change the data we hold about you.

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/
- at http://www.newcastle-hospitals.org.uk/about-us/freedom-of-information_how-we-use-information.aspx
- our information document available from the research team at your hospital site
- by asking one of the research team

What will happen if I don't want to carry on with the study?
Participation in any research study is completely voluntary and you can decide to withdraw from the study at any time. Withdrawing from the study will not affect the care you already receive from your own Consultant. If you do decide to withdraw from the study, we will retain and use all data provided up to the point of withdrawal.

What if something goes wrong?
In the event that something does go wrong and you are harmed during the study there are no special compensation arrangements that are different to the normal ones for NHS care. If

you are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the Trust or Hospital. The normal National Health Service complaints mechanisms will still be available to you.

What will happen to the results of the research study?
The overall results of this study will be published in a medical paper, but your identity will not be revealed. You can be informed of the final study results once all the data has been collected and analysed.

Who is organising and funding the research?
The study is sponsored and hosted by Newcastle University and Newcastle upon Tyne Hospitals NHS Foundation Trust. The British Heart Foundation has provided funding for this study.

Who has reviewed the study?
This study has been ethically reviewed by NHS Research Ethics Committees in England and Scotland. The NHS Health Research Authority a national body that promotes the interests of patients and the public in research has also reviewed it.

How have patients and the public been involved in this study?
We have already shared our plans for this study with the Patient and Public Involvement organisation, VOICE, Newcastle University. One member of VOICE is also a Trial Steering Committee member and invited to give their views as the study progresses. Once the study is completed, the patient group will also support with the dissemination of study findings to the lay public and patients.

Contact Details:
For further information about the study please contact:
(PLEASE PROVIDE LOCAL RESEARCH TEAM CONTACT DETAILS)
Name:
Address:
Telephone number:

Thank you for taking the time to read this information sheet.

The British Heart Foundation older patients with non-ST SEgmeNt elevatIOn MyocaRdial Infarction Randomised Interventional TreAtment Trial (The BHF SENIOR-RITA Trial)

Participant Consent Form

Participant ID: |___|___|___|___|___|___|
Site Principal Investigator: _____

Please initial boxes

- I have read and understood the information sheet (Version _____ dated _____) for the above study. I have had the opportunity to consider the information and ask questions. These questions have been answered to my satisfaction. ☐
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. I also understand that the investigator in charge of this study may decide at any time that I should no longer participate in this study. ☐
- I understand that relevant sections of my medical notes and data collected during this study may be looked at by individuals from Newcastle University Clinical Trials Unit, research Sponsor, regulatory authorities or from the NHS trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
- I agree to provide my address and contact details so that study staff may follow-up by phone and/or send study related materials by post to my home address. ☐
- I agree to my GP being informed of my participation in this study ☐
- I give permission for the collection via the Health and Social Care Information Centre (HSCIC) of my health related data from the Hospital Episode Statistics (HES), and the Office of National Statistics (ONS) databases, and medical/GP records. ☐
- I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers. ☐
- I agree to participate in this study ☐

Name of Participant (PRINT)	Date	Signature
Name of Person taking Consent (PRINT)	Date	Signature

Original for Investigator Site File; 1 copy for participant; 1 copy for hospital notes; 1 copy sent to NCTU