The British Heart Foundation older patients with non-ST SEGMENT ELEVATION Myocardial Infarction Randomised Interventional Treatment Trial (The BHF SENIOR-RITA Trial)

Consultee Information Sheet & Consultee Declaration Form

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

Study Local Principal Investigator Name:

We have given you this information sheet as you have kindly agreed to act as a consultee for your relative or friend who has had a heart attack. We feel that your relative/friend is unable to decide whether to participate in our research study. To help decide if they should join the study we would like to ask your opinion on whether they would wish to be involved. Please consider what you know about their wishes and feelings, and consider their interests. Please also let us know about any advance decisions they may have made about participating in research. These will take precedence.

If you decide your relative/friend would have no objection to taking part in this research study we will ask you to read and sign the consultee declaration form. We will keep you fully informed during the study so you can let us know if you have any concerns or you think your relative/friend should be withdrawn.

If you decide that your relative/friend would not wish to take part, it will not affect the standard of care they receive in any way. If you are unsure about taking the role of consultee you may seek independent advice. We will understand if you do not want to take on this responsibility. The following information is the same as would be provided to your relative/friend.

We would like to invite your relative/friend to take part in a research study called The BHF SENIOR-RITA Trial. Their participation in this study is voluntary. If you believe that they would not want to participate in the study, this will not affect their 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 relative/friend's 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 on your relative/friend before you sign the consultee declaration form to participate in the study.
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 is my relative/friend being invited to take part?
Your relative/friend is being invited to take part in this research study because they have suffered a heart attack and they are 75 years of age or older.

Do they have to take part?
No, it is entirely up to you to decide whether or not your relative/friend should take part. Your relative/friend is 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 your relative/friend will receive now or in the future. If you decide that your relative/friend should not take part in this study, they will receive normal treatment and it will not be changed in any way.

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

**Invasive Treatment:** Your relative/friend will undergo the heart artery X-ray test, called coronary angiography. For this procedure, your relative/friend’s Cardiologist will insert a small tube in their wrist or groin area using a small puncture in the skin. Tubes will then be advanced through blood vessels to locate the heart arteries, dye will be injected and X-ray pictures of the heart arteries taken. This will show whether your relative/friend has any blockages in their heart arteries. Your relative/friend’s Cardiologist will then discuss with you whether to treat the blockages with coronary angioplasty (inflating a balloon to open the artery and allow blood flow) or refer them 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 your relative/friend.

No matter which group your friend/relative were in, routine care will be given in the usual way. At some hospitals, if your friend/relative were randomised to receive an angiogram
they may have to be moved to another hospital for that. The person who invited them to take part will be able to tell you if that would apply to your friend/relative. 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:** Your relative/friend will receive the latest medications to treat patients with heart artery disease. However, they will not undergo a coronary angiogram unless your relative/friend’s condition changes and they need to have this procedure.

It is important to understand that neither you nor your relative/friend’s cardiologist can decide which of the two treatment options they will have. The computer will select their treatment at random. To take part you must be prepared for your relative/friend to have either option. We hope to recruit 2300 patients to the SENIOR-RITA trial from 30 centres all across the UK. We will then be able to evaluate which one of the two treatment groups is best.

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

**What happens in subsequent follow-ups?**
We will follow your relative/friend up in the clinic, through telephone calls or through postal questionnaires at 1, 3, 6, and 12 months, and yearly thereafter for 5 years. At 1, 3, 6 months and at 1, 2, 3, 4 and 5 years after starting the study we will ask your relative/friend or their carer, if your friend/relative is 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 your relative/friend is feeling, whether they are using health and social services and what costs are incurred by your relative/friend in managing their heart condition; we will collect this information by questionnaires that can be completed at home or by phone. In addition, we will collect information from your relative/friend’s medical records on any important medical events they have experienced and the medications they are taking since they were included in the study. We will reassess their mental capacity at 1 year and frailty at 6 months and 1 year. We will measure their frailty status yearly thereafter for 5 years. All this information will be collected at 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. Pre-paid envelopes for return of any required information by post to the study team will be provided. 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 my relative/friend be involved in the study?**
Your relative/friend’s participation in the study will be expected to last 5 years. After this, with your permission, we will continue to collect your relative/friend’s health related data via their Health Record and the Office of National Statistics database (Hospital Episode statistics) for an additional 5 years.

**Will I be paid for participating in the study?**
Neither you nor your relative/friend will 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, your relative/friend will continue their usual follow up arrangements with their 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.

**Will my relative/friend taking part in the study be kept confidential?**
By agreeing for your relative/friend to take part in this study you are also agreeing to the study staff collecting personal data about your relative/friend, including the following: their date of birth, sex, race or ethnic origin, details of their medical condition, their NHS number, both of your addresses and contact details (only for completion of required study questionnaires). In addition copies of signed declaration forms will be sent to the Clinical Trials Unit where they will be stored securely.

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 your relative/friend will be given a unique study number under which all data and test results will be entered. Your
relative/friend’s 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 and your relative/friend as research participants and nothing that could reveal your or your relative/friend’s identity will be disclosed outside the research site. All the information about your participation and your relative/friend’s participation in this study will be kept confidential. With your permission we will notify your relative/friend’s GP that they are taking part in this study. Participation in the study will also be noted in your relative/friend’s hospital records. If you agree we will link your relative/friend’s NHS number and postcode to their participant data file held in the encrypted data storage data base to allow continued follow up linked to a national database (National Hospital Episode Statistics).

**What will happen if I don’t want my relative/friend to carry on with the study?**

Participation in any research study is completely voluntary and your relative/friend can decide to withdraw from the study at any time. Withdrawing from the study will not affect the care your relative/friend already receives from their own Consultant. If they 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 your relative/friend is harmed during the study there are no special compensation arrangements that are different to the normal ones for NHS care. If your relative/friend is harmed and this is due to someone’s negligence then they 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 and your relative/friend.

**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 relative/friend’s 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. Funding for this study has been provided by the British Heart Foundation.

**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, VoiceNorth, Newcastle University. One member of VoiceNorth 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.
NHS Complaints Procedure
LOCAL SITE PROCEDURE CONTACT INFORMATION TO BE ADDED HERE e.g., PALS)

Contact Details:
For further information about the study please contact:
(Please provide local research team 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 Randomized Interventional TreAtment Trial (The BHF SENIOR-RITA Trial)
Consultee Declaration Form

Participant ID: | ___ | ___ | ___ | ___ | Site number: _______________
Study Principal Investigator: ____________________________________________

Please initial boxes

• I have been consulted about relative/friend’s participant in this research study. I have read and understood this information sheet (Version _____ dated ______) and have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction.
• In my opinion my relative/friend would have no objection to taking part in the above study.
• I understand that I can request that my relative/friend is withdrawn from the study at time, without giving any reason and without their harming future medical care or losing any legal rights or benefits that might be otherwise entitled. I also understand that the investigator in charge of this study may decide at any time that my relative/friend should no longer participate in this study.
• I understand that relevant sections of their medical notes and data collected during this study may be looked at by individuals from the research Sponsor, Newcastle University Clinical Trials Unit, regulatory authorities or from the NHS trust, where it is relevant to taking part in this research.
• I agree to provide address and contact details for myself and my relative/friend so that study staff may follow-up by phone and/or send study related materials by post.
• I agree to my relative/friend’s GP being informed of their participation in this study.
• I give permission for the collection via the Health and Social Care Information Centre (HSCIC) of my relative/friend’s health related data from the hospital episode statistics (HES) from their health record and the Office of National Statistics (ONS) databases for the duration of the study an additional 5 years after their participation in the study ends.
• I understand that information collected about my relative/friend will be used to support other research in the future and may be shared anonymously with other researchers.

Name of Consultee: _________________________ Date______________ Signature_________________________
Relationship to participant: _______________________________

Person undertaking consultation (if different from researcher)
Name _________________________ Date______________ Signature_________________________

Researcher: _________________________ Date______________ Signature_________________________

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes; 1 copy sent to NCTU.