Participant Information Sheet

THE SCOT-HEART 2 TRIAL

You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The purpose of the study is to determine the best way of preventing heart attacks.

Currently, Doctors use a 'risk score' (or ASSIGN score) to help them decide who needs advice and medication to prevent heart attacks. These scores look at factors such as age, smoking habit and whether heart disease runs in the family. However, these scores are not always accurate and can mean that some patients are given unnecessary medication and others are not given the medication they need.

Alternatively, we can screen for heart disease using a specialised scan. In a previous study (the first SCOT-HEART trial), we showed that a CT scan changed the way patients with symptoms of heart disease were diagnosed and treated, and fewer people went on to have heart problems. However, this scan is an extra test and uses radiation as well as requiring the administration of some drugs.

In the SCOT-HEART 2 trial, we will recruit at least 6,000 people from Scotland who are at risk of heart disease and will compare two ways of deciding how to prevent future heart problems. We will compare the current standard of care, using a Scottish 'risk score', with a CT scan to look at the heart. This will help us find out if making decisions based on the results of a CT scan will stop too many people being given medicines they don't really need, and see whether it lowers the number of people developing heart disease.

Why have I been invited to take part?

You are invited to take part if you are between 40-70 years old, live in Scotland and may be at risk of developing heart disease.

Do I have to take part?

No, it is up to you to decide whether or not you take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights. Before taking part, you should consider if this will affect any insurance you have and seek advice if necessary.

What will happen if I take part?

If you are interested in taking part, you can make an appointment with the research team at the Western General Hospital in Edinburgh.

APPOINTMENT 1: We will complete a review to see if you are suitable to take part in the study and answer any questions you have. If you agree to take part, we will ask you to sign a consent form. If you are female, and think you might be pregnant, we will ask you to take a pregnancy test before you enter the trial as the radiation exposure from CT scans is not advisable for pregnant women. You will then be randomly assigned (like flipping a coin) by computer to either the ASSIGN risk score or a CT scan of the blood vessels in your heart. We will ask you to complete a questionnaire about your lifestyle and quality of life and take some blood (two tablespoons or 30 mL) and measure your blood pressure. The sample will be used to check your cholesterol level and kidney function, and the remaining blood will be kept (with your permission) for use in future research.

APPOINTMENT 2 (CT scan group only): If you are in the group having a CT scan, you will attend one further appointment <at the Royal Infirmary> to have this test.

What happens during the CT scan?

The test uses an x-ray machine to give a detailed 3D picture of your heart and its blood vessels. Doctors use the pictures from the scan to help diagnose heart disease. In order for the scanner to get a clear picture of the heart, you are given a substance called a “contrast agent” through a small plastic tube placed in the vein in your arm. It is common to feel a warm sensation as this passes through your body. Some patients experience a metallic taste in their mouth which lasts for less than a minute. You may also be asked to have beta blocker or GTN medicines to slow the heart rate and get better pictures. You may experience headaches, tiredness, dizziness or light-headedness, flushing or a warm feeling in the face for a short time after taking these medicines although many people do not notice these effects. You will also have a CT calcium score during the scan to measure the amount of calcified, or hardened, plaques in the arteries. As with the CT scan it’s used to rule out heart disease. A low calcium score is useful because it indicates that it’s highly unlikely that you have coronary heart disease. During the scan, you will lie on a bed in a well-lit, spacious room. The bed will pass into a wide ‘doughnut’ shaped part of the scanner. You simply lie still and take a deep breath while images are taken. Your appointment will take about 1 hour; the scan itself is a short part of this.

An example of a CT scan of the chest

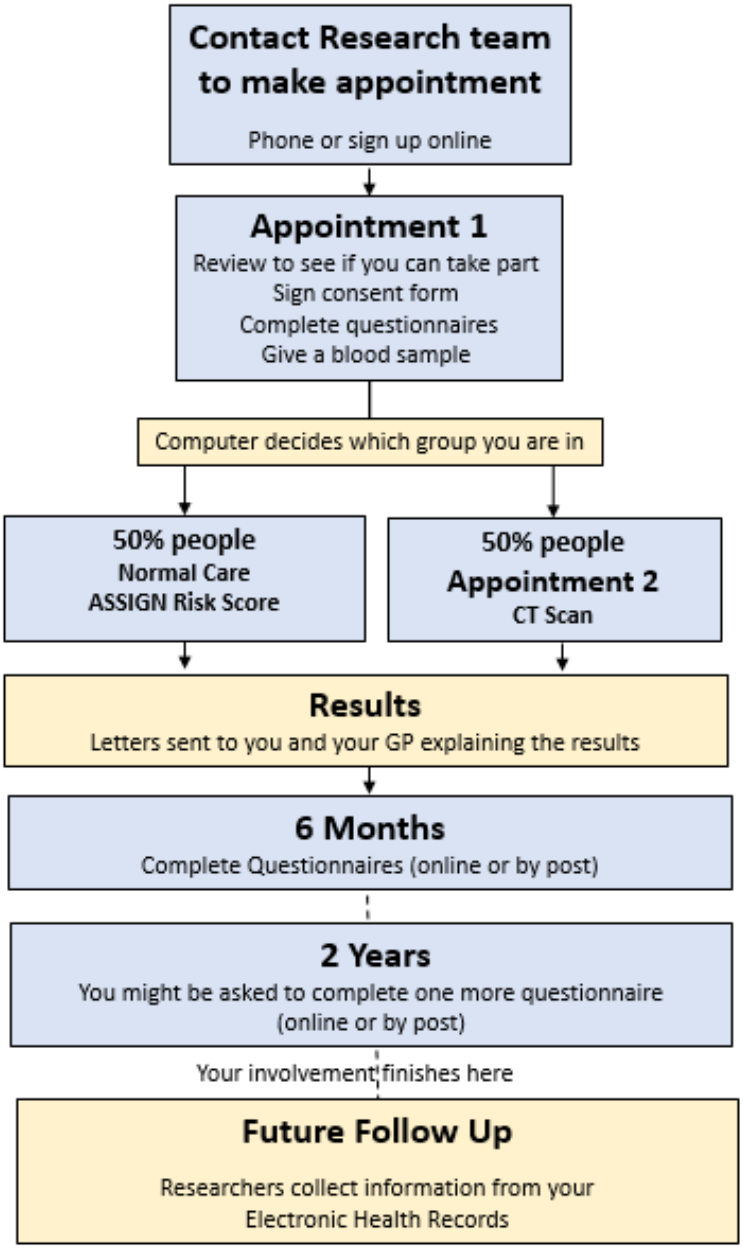
Reasonable travel expenses can be given for study appointments.

RESULTS: Once the research team have completed your ASSIGN score or CT scan, they will use the results to advise you and your GP by letter about whether or not you need to change your lifestyle or take medications to prevent heart disease. You should make an appointment with your GP to discuss any changes in medications. If the CT scan showed blockages in the vessels of your heart or an unknown health condition that need further follow up at the hospital, we would notify you about this and arrange an appointment.

FOLLOW UP

QUESTIONNAIRES: You will be asked to complete a questionnaire online or by post at the first visit and at 6 months after you join the study. Some participants will be contacted again at 2 years and asked to complete one further questionnaire. We will not contact you again after the final questionnaire has been returned.

ELECTRONIC MEDICAL RECORDS: We also seek your permission to do long-term review of your medical records to see whether any treatments you were given helped stop you from developing heart disease, other health related problems, and if you needed any further hospital care. This will help us to see if the ASSIGN score or CT scan made a difference over a much longer time. This would involve us asking for information from the central NHS registers at fixed points in the future. For example, for the first SCOT-HEART study, we reviewed the medical records of the participants at 2 and 5 years after the study finished, and it provided very valuable findings for our research. We will continue to review the records for 10 or more years. To do this, we'll need to collect your unique patient identifier (CHI number) and store it at the University of Edinburgh.



What are the possible benefits and disadvantages of taking part?

The study involves coming to an appointment at the Western General Hospital and completing questionnaires during the time you are taking part.

If you are in the group receiving CT scan and calcium score scan there may be additional benefits and disadvantages to taking part and you will have to attend an additional visit at the Royal Infirmary Edinburgh. If you receive a CT scan it is possible that the results of the scan will help decide whether or not there is any narrowing or blockage of the blood vessels around your heart and whether this means you should be taking medications. It may also show additional unknown problems in the heart and chest that may not have been found otherwise. If this were to happen, your GP would be made aware of these findings and we will arrange any further tests or treatments you need.

If you take part in this study you may have a CT scan and CT calcium score scan. This exposure will be extra to those that you would have if you did not take part in the trial. This procedure uses ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. We are all at risk of developing cancer during our lifetime. The normal risk is that this

will happen to about 50% of people at some point in their life. Taking part in this study will increase the chances of this happening to you from 50% to up to 50.17 %. You should not be exposed to radiation if you are pregnant or breastfeeding.

There is a very low risk of developing a reaction to the contrast agent used in the scan. This usually involves an itchy rash that settles down by itself. Occasionally people require additional medications for this. If you are known to have an allergy to the contrast agent, you will not be eligible to take part in the study.

In patients with mild kidney disease, there is a very small risk that the use of contrast agent may worsen this kidney damage. This is rare and is usually temporary. We take a blood test to check the health of your kidneys when you join the study and will not carry out the scan if we think you are at risk of harm.

We hope that the research will benefit many more people by helping us decide the best way to treat patients like you in the future.

What if there are any problems?

If you have a concern about any aspect of this study please contact <insert name and contact details of WTCRF> who will do their best to answer your questions.

In the unlikely event that something goes wrong, 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 against NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What will happen if I don't want to carry on with the study

If you no longer want to take part in the trial, you can stop at any time and without giving a reason. If you do not want to attend the CT scan appointment but are still happy to complete questionnaires or for us to collect information from your medical records then we will give you this option if you chose to stop the study. If you no longer wish us to keep your blood samples for future research, then you should contact us so these can be destroyed. If you do stop, any information already collected for the study will be kept by us and used as part of the results.

What happens when the study is finished?

All the data collected will be kept securely for 3 years after the study has been finished in case it needs to be reviewed again. The data will then be anonymised and stored securely by the University of Edinburgh for use in future research.

The blood samples collected will be held by the University of Edinburgh in a secure storage facility. The samples will only be identified by a lab number and may be used for future studies. There is no time limit on how long these will be kept. Future research may involve the analysis of deoxyribonucleic acid (DNA - the molecule that contains your genetic code) to look for genetic links with heart disease or other health problems. The samples may be sent abroad or shared with other researchers. The results of these tests will not be available to you or your doctor as it will all be carried out anonymously.

Your medical records will continue to be reviewed in the future as part of long term follow up as described on page 2. We'll periodically ask central NHS registers to give us information about your health (you won't be contacted directly for this). Any data collected in the future will be handled in the same way.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. For details on what data will be held about you and who will hold and store this information please refer to the Data Protection Information Sheet.

What will happen to the results of the study?

This study results will be published in a medical journal and will be shared with other medical professionals at meetings and conferences. You will not be identifiable from any published results. The results of the study will be made available to you once it has finished on the study website: https: //edin.ac/scotheart2

Who is organising and funding the research?

This study has been organised by Prof David Newby (Consultant Cardiologist at the Royal Infirmary of Edinburgh) and Edinburgh Clinical Trials Unit. It is sponsored by The University of Edinburgh and NHS Lothian (ACCORD), and is being funded by the British Heart Foundation (CS/18/4/34074) and Chief Scientist Office.

Who has reviewed the study?

The study proposal has been reviewed by the British Heart Foundation. Patient and Public Involvement (PPI) representatives helped review the study documents. All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been given by South East Scotland REC 02. NHS Lothian Health Board have also approved the research.

Researcher Contact Details

If you have any further questions about the study or would like to take part please contact <insert name> on <insert phone number> or email on: <insert email address>.

You can also sign up online by going to https: //edin.ac/scotheart2.

Independent Contact Details

If you would like to discuss this study with someone independent of the study, please contact Dr Nick Cruden on 0131 242 1843.

Complaints

If you wish to make a complaint about the study please contact:

Patient Experience Team
2 – 4 Waterloo Place, Edinburgh, EH1 3EG
Email: feedback@nhslothian.scot.nhs.uk Tel: 0131 536 3370