DIVISION OF CARDIOVASCULAR MEDICINE

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Oxford University Hospitals NHS
NHS Foundation Trust

PARTICIPANT INFORMATION SHEET

Magnetic resonance guided radiotherapy to the stellate ganglia for ventricular arrhythmia

We would like to invite you to join this study. To help you decide if you are interested in participating in this study we are providing this participant information sheet. It is important for you to understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask. Remember it's your choice and you will be able to withdraw at any time should you wish.

Key facts:
We are investigating a new treatment to reduce dangerous rhythms in the heart and prevent sudden cardiac death in patients at high risk of this. We are including patents with an implantable cardioverter defibrillator who have recently required therapy from their device for a dangerous heart rhythm.

What will this entail for me?

- Your involvement in this study will be over a period of up to 9 months and will involve a total of 9 visits with the study team.
- During this time you will have two MRI scans of your heart and neck and one CT scan of your heart and neck
- You will receive three radiotherapy treatments to the nerves in your neck that normally stimulate the heart.
- Over the course of the study you will also have six blood samples taken
- We will ask you to complete a questionnaire about how your heart condition affects your quality of life.
- Throughout the study your ICD device will be remotely monitored as part of your routine care at the pacing clinic. We will use this information to measure your average heart rates and see if you have required any treatments from the device.

Are there any risks?

- If you take part in this study you will receive radiotherapy treatment. Radiotherapy uses high doses of radiation to treat disease. Radiotherapy is entirely new in treating your clinical condition, but you will receive a radiotherapy dose that is not unusual for standard radiotherapy treatment. The radiation will be highly targeted but there will still be some wider radiation beyond the precise area we are treating. Radiotherapy is associated with a multiple potential treatment side-effects detailed in section 6. In the long term, radiation may cause cancer many years or decades after the exposure. The risk of developing cancer as a consequence of radiotherapy treatment is an accepted side-effect of the treatment and must be balanced against the potential overall benefit of receiving radiotherapy. The radiation dose from the CT scan you will receive as part of this study will be very small compared to the dose from the radiotherapy treatment. The highest radiation risk for inducing cancer will be incurred by the radiotherapy treatment (a known potential complication) and this risk will not be significantly altered by the inclusion of the CT scan.
- Radiotherapy has not been used before the treat your clinical condition. It is thus possible that unforeseen and potential serious complications could occur.
- MRI scanning is safe and should not affect your ICD device. As part of the routine MRI scan procedure we will temporarily reprogram your device into an MRI safe mode for the duration of the MRI scan.

Contents

1.What is the purpose of the study?

Life threatening heart rhythms are often triggered by groups of nerves that speed up the heart, which are located in your neck. Patients with certain heart conditions such as heart failure are at particular high risk of these rhythms that can lead to sudden cardiac death. To date there are only limited treatment options available to prevent these dangerous rhythms from occurring. Surgically removing the nerves that stimulate the heart is a promising treatment for patients with recurrent dangerous heart rhythms, but the risk of complications from the surgery is high, so this is only used as a last resort.

Recently magnetic resonance (MR) -guided radiotherapy has improved the precision and accuracy of radiotherapy treatment for cancer. This new technology offers the ability to precisely target tissues with submillimetre accuracy without damaging sensitive organs nearby. We think this technology can be used to modify the nerves that stimulate the heart, thus reducing dangerous heart rhythms without the need for surgery.

We designed this study to test if using MR guided radiotherapy can be used to safely modify the nerves that stimulate the heart, and if this results in a reduction in dangerous heart rhythms. We will also take blood samples to measure bio-markers commonly associated with dangerous heart rhythms to help us better understand your heart's response to this treatment.

We will use MR guided radiotherapy to target the nerves in your neck that stimulate the heart. By using radiotherapy we will be able to gradually modify these nerves in small steps over the course of 3 treatments.

Overall we hope this study will lead to a safe and effective treatment to prevent dangerous heart rhythms.

2.Why have I been invited?

You have been invited to take part in this study because you have an implantable cardioverter and defibrillation device (ICD) that has recently delivered treatment for dangerous heart rhythms. You many have been informed of this study by your normal clinical team and contacted the research team yourself, or with your agreement your contact details have been passed on to us.

This study will be inviting 13 adults with heart failure and MRI conditional ICDs who have recently required treatment from their ICD for dangerous heart rhythms.

3.Do I have to take part?

No, you do not have to take part.

It is up to you to decide whether or not to take part. Even if you decide to take part, you are free to change your mind and leave the study at any time, without giving a reason. This would not affect the standard of clinical care you receive now or in the future. If you do decide that you no longer wish to continue with the study, we would still retain any data and samples already obtained from you unless you request otherwise.

4.What will happen to me if I decide to take part?

If you decide to take part in this study there will be no changes to your clinical care.

You will be asked to attend 1 screening visit and 8 study visits over the course of 9 months. In addition to this your ICD device will be remotely monitored by the pacing clinic as part of their usual care, and we will use this information to assess the effectiveness of the treatment.

Visit 1 – Screening visit

This visit will be at the John Radcliffe Hospital in Oxford and is designed to formally assess if you are eligible and it is safe for you to take part in our study. You will have an opportunity to go through this information leaflet with the study team who can answer any questions you have and, if you still want to take part, will ask you to sign a screening consent form.

The following procedures will take place during this visit:

- **Screening consent (20 minutes):** We will go through the information leaflet and explain the study to you in detail. We will address any questions you have about our study. Once we are sure you understand all the study procedures and potential risks associated with this, and you are still willing to participate in our study, we will ask you to sign a consent form.

- **Medical history (5 minutes):** To confirm you are eligible and it is safe for you to take part in this study we will ask you questions about your past medical history. We will also ask for access to your medical records to get relevant information for the study, such as medication history, and your past medical history.

- **Physical examination (5 mins):** This is to ensure that you do not have any cardiac condition that prevents you from taking part in this study. This will include measurements of your height and weight and blood pressure.

- **Kansas City Cardiomyopathy Questionnaire (5 minutes):** To assess how your heart condition is affecting your quality of life, we will ask you to complete a short questionnaire.

- **Electrocardiogram (ECG) (5 mins)**: 12 small electrode pads will be placed on your chest to take a single recording of the electrical activity of the heart. This can be done by a member of staff of the same gender as you, if you would prefer.

- **Cannulation (5 mins):** We will insert a needle connected to a small plastic tube into a vein on the the back of your hand or elbow. This will allow us to inject contrast for your MRI scan. Please let us know if you would like to lie down while this is done. The tube will be removed after your scan.

- **MRI scan (60-90 mins):** You will have an MRI scan of your neck and heart using gadolinium based contrast. The MRI scanner is shaped like a long doughnut (see picture on the next page), with a tunnel inside measuring about 60 centimetres wide. You will be asked to lie still on your back while your heart is scanned. You may be asked to breathe in and out and hold your breath for several seconds for some of the scans. The MRI machine can make loud noises so you will be given ear protection. You will be able to communicate with the radiographer at all times. A pacing clinic physiologists will be in attendance to ensure that your ICD device is MRI safe and does not get damaged by the MRI scan.

Once you have completed all the screening tests you can go home. A member of the research team will then be in touch with you about the results of these tests. If you meet the criteria to continue with this study the next steps are outlined below. If the results of your assessment indicate that you are not able to continue with the study, the study team will explain why, and no further study visits will be required. You would exit the study at this point.

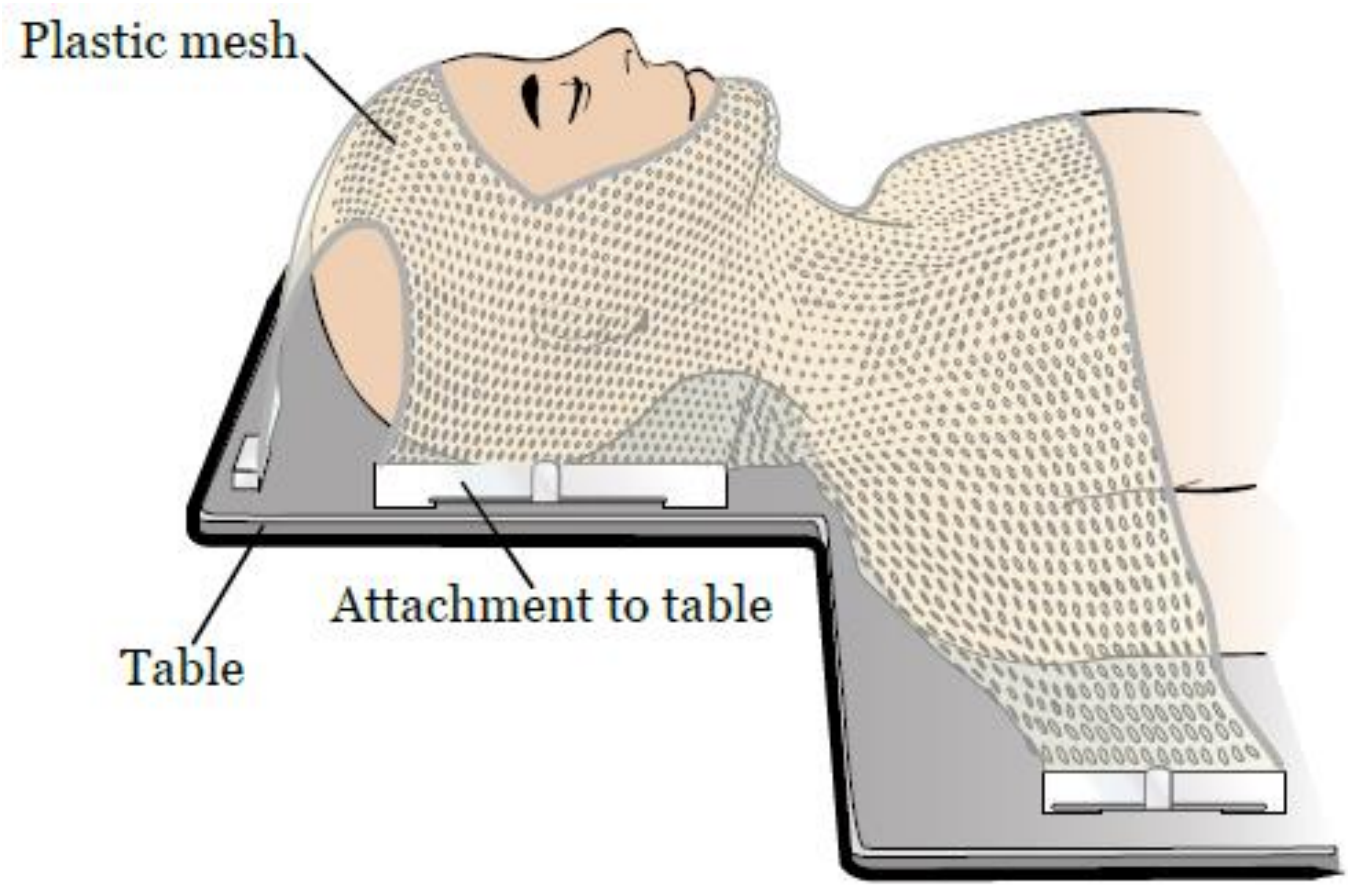
Visit 2 – Radiotherapy team visit and formal study consent

This visit will be at the radiotherapy treatment centre at GenesisCare in Oxford. During this visit you will meet the team who will plan and deliver your radiotherapy treatment. During this visit the team will go through all the details of your radiotherapy treatment, and explain any potential side effects or risks associated with it. You will have the opportunity to ask any questions you have about your radiotherapy treatment. If at the end of this consultation you are still willing to proceed with the radiotherapy treatment we will ask you to sign the full study consent form and you will be formally enrolled in our study from this point. This visit will last approximately 1 hour.

Visit 3 – Planning scans

This visit will be at the radiotherapy treatment centre at GenesisCare in Oxford. This visit will consist of two scans to help us plan your radiotherapy treatment. They will allow us to individually tailor your radiotherapy treatment and adjust the radiotherapy dose to a safe level for you.

- **Mask fitting (10 minutes)**: To help position you as accurately as possible for your radiotherapy threatment, we will mold a plastic mask to fit over your head, neck and shoulders. Your face will be un-covered (see image below). This mask is then attached to the radiotherapy table during your radiotherapy treatments to ensure your head neck and shoulders are in the exact same position every time.



Cannulation (5 mins): We will insert a needle connected to a small plastic tube into a vein on the the back of your hand or elbow. This will allow us to inject contrast for your MRI and CT scan. Please let us know if you would like to lie down while this is done. The tube will be removed after your scans.

- **Pregnancy screening (1 minute):** If you are a woman of child bearing age (below the age of 55 years) it is standard clinical practice to make sure you are not pregnant before any scan involving radiation. The team doing your scan will ask you some questions to determine if there is any chance that you could be pregnant. If pregnancy cannot be ruled out based on these questions, we may ask you to do a pregnancy test before your scan.

- **Computed Tomography (CT) scan (30 minutes**): You will have a CT scan of your neck and chest. The scanner is shaped like doughnut with a hole in the middle. You will be asked to lie still on your back while you are scanned. You may be asked to breathe in and out or hold your breath for several seconds for some of the scans. During the scan there will be an injection of contrast into your arm which may briefly feel like a hot flush.

- **MRI scan (60-90 minutes):** During this visit you will have a further MRI scan using the radiotherapy specific MRI scanner (MR-Linac). This will be similar to the MRI scan you had on your first visit.

Visits 4 to 6 – Radiotherapy treatment

These three visits will take place at the radiotherapy treatment centre at GenesisCare in Oxford, where you will receive radiotherapy treatment to the nerves in your neck that stimulate the heart. Your treatment will be delivered on alternate days over the course of 1 week. In the presence of unforeseen circumstances (such as not being able to attend your appointment for any reason, or due to changes in availability of the radiotherapy machine) we can be flexible to re-schedule your radiotherapy appointments as long all radiotherapy treatments occur within a two week window.

- **Pregnancy screening (1 minute):** If you are a woman of child bearing age (below the age of 55 years) it is standard clinical practice to make sure you are not pregnant before any scan involving radiation. The team doing your scan will ask you some questions to determine if there is any chance that you could be pregnant. If pregnancy cannot be ruled out based on these questions, we may ask you to do a pregnancy test before your scan.

- **Physical examination (10 mins):** Before and after each radiotherapy treatment we will perform a cardiovascular examination including blood pressure and heart rate. We will also perform a neurological examination of the nerves in your face and arm. This will allow us to detect any side effects from the radiotherapy.

- **Electrocardiogram (ECG) (5 mins)**: 12 small electrode pads will be placed on your chest to take a single recording of the electrical activity of the heart. This can be done by a member of staff of the same gender as you, if you would prefer.

- **Blood sample collection (10 minutes):** Before each radiotherapy session we will collect blood samples. This will involve a small needle into a vein in the back of your hand or elbow to allow us to collect up to 16 ml (about 3 teaspoons) of blood.

Radiotherapy (60 minutes): We will deliver radiotherapy using the MR Linac machine (imaged on the right). You will be positioned in the MR-Linac in the same position as your planning MRI scan, with your mask in place. The MRI-Linac can make loud noises so you will be given ear protection. You will be able to communicate with the radiotherapy staff at all times. A pacing clinic physiologist will be in attendance to ensure that your ICD device is MRI safe and does not get damaged by the MRI scan or radiotherapy. The treatment will take up to 60 minutes. This will include new additional imaging, adjusting the bed position to ensure it is optimal for treatment, optimisation of the treatment plan and treatment delivery. You will feel no pain during this treatment.

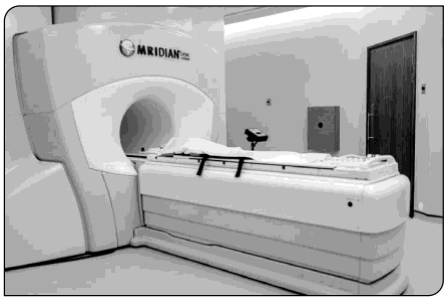


Photo of the MR Linac in Oxford courtesy of GenesisCare

Visit 7 and 8 - follow-up visits

These follow up clinic visits will be at the John Radcliffe hospital. They will be planned to occur at 6 weeks and 3 months after your last radiotherapy treatment.

- **Physical examination (5 mins):** We will perform a cardiovascular examination including blood pressure and heart rate. We will also perform a neurological examination of the nerves in your face and arm. This will allow us to detect any side effects from the radiotherapy.

- **Kansas City Cardiomyopathy Questionnaire (5 minutes):** To assess how your heart condition is affecting your quality of life we will ask you to complete a short questionnaire.

- **Symptom Questionnaire (5 minutes):** To ensure we don't miss the presence of any side effects from the radiotherapy we will ask you to complete a questionnaire that will ask you about any possible radiotherapy related symptoms you might be experiencing.

Electrocardiogram (ECG) (5 mins): 12 small electrode pads will be placed on your chest to take a single recording of the electrical activity of the heart. This can be done by a member of staff of the same gender as you, if you would prefer.

- **Blood sample collection (5 minutes):** We will collect blood samples at both these visits. This will involve a small needle into a vein in the back of your hand or elbow to allow us to collect up to 16 ml (about 3 teaspoons) of blood.

Visit 9 – Final study visit

Your final study clinic visit will be 6 months after your last radiotherapy treatment, at the John Radcliffe Hospital. This visit and will include a final MRI scan to assess your heart function and look for any physical changes to the nerves in your neck that were treated with radiotherapy.

- **Physical examination (5 mins):** We will perform a cardiovascular examination including blood pressure and heart rate. We will also perform a neurological examination of the nerves in your face and arm. This will allow us to detect any side effects from the radiotherapy.

- **Kansas City Cardiomyopathy Questionnaire (5 minutes):** To assess how your heart condition is affecting your quality of life we will ask you to complete a short questionnaire.

- **Symptom Questionnaire (5 minutes):** To ensure we don't miss the presence of any side effects from the radiotherapy we will ask you to complete a questionnaire that will ask you about any possible radiotherapy related symptoms you might be experiencing.

Electrocardiogram (ECG) (5 mins): 12 small electrode pads will be placed on your chest to take a single recording of the electrical activity of the heart. This can be done by a member of staff of the same gender as you, if you would prefer

- **Blood sample collection (5 minutes):** We will collect a final blood sample during this visit. This will involve a small needle into a vein in the back of your hand or elbow to allow us to collect up to 16 ml (about 3 teaspoons) of blood.

- **MRI scan (60-90 mins):** You will have a final MRI scan of your neck and heart. This will be identical to the MRI scan you had during your first visit.

5.What should I consider?

- If you have a history of kidney disease, or other severe illnesses you might not be able to participate in the study.

- In addition, if you are pregnant, breast feeding or planning to become pregnant during this study period you may not be able to participate in the study.

- If you are involved in other research studies, you should inform the investigators prior to your enrolment in this study.

- If you are unable to undergo an MRI scan: we cannot scan someone if they are claustrophobic or have specific metallic implants or devices. If you are unsure about this please get in touch with us to clarify if you are safe to have an MRI scan.

6.Are there any possible disadvantages or risks from taking part?

Taking part in this study will involve some risks that are described below. At all times, an experienced study investigator will be with you and will address appropriately any issues that may arise.

Radiotherapy: If you take part in this study you will receive radiotherapy treatment. Radiotherapy is entirely new in treating your clinical condition. Radiotherapy uses high doses of radiation to treat disease, and if you take part in this study you will receive a dose that is not unusual for standard radiotherapy treatment. The radiation will be highly targeted but there will still be some wider radiation beyond the precise area we are treating.

Radiotherapy is associated with a multiple potential treatment side-effects. In the short term this may include temporary mild tiredness, discomfort swallowing or a cough. Less commonly a localised skin reaction or hair loss at the base of the neck/upper body can occur. In the long term, there is a theoretical low risk of damage to your wind pipe and food pipe leading to narrowing of the food pipe, or injury to nerves in your shoulder resulting in pain, numbness and tingling sensations in the arms. Finally because the use of

radiotherapy is entirely new in treating your clinical condition, there is a theoretical risk of unforeseen complications.

Ionising radiation exposure: In the long-term radiation may cause cancer many years or decades after the exposure. The risk of developing cancer as a consequence of radiotherapy treatment is an accepted side-effect of the treatment and must be balanced against the potential overall benefit of receiving radiotherapy.

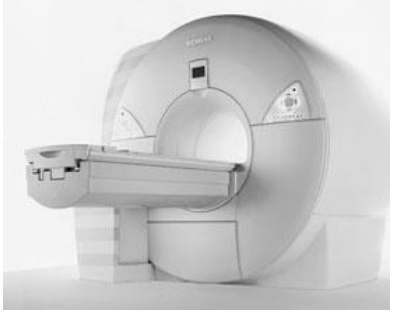
The radiation dose from the CT scan you will receive as part of this study will be very small compared to the dose from the radiotherapy treatment. It is equivalent to 4 years of the background radiation to which you are exposed in everyday life in the UK.

Cardiac sympathetic denervation: This is the medical term used to describe the process of modifying the nerves that stimulate the heart, which is the aim of this study. The heart can continue to function normally without these nerves. It is possible to experience low blood pressure following your treatment but this is only temporary. It is also possible to damage nerves that supply the upper limb and face. This can lead to pain or altered sensation and sweating in the upper limb and face. Rarely it is possible to develop Horner's syndrome which is a combination of a dry eye, drooping eyelid and constricted pupil. In the majority of cases such side effects are temporary and mild. Furthermore our study is designed specifically to minimise such side effects by providing radiotherapy over 3 steps to allow us to detect the development of side effects early, and stop treatment before any damage is permanent.

MRI: An MRI scan is safe and non-invasive and does not involve any ionising radiation (x-rays). However, because it uses a large magnet to work, MRI scans are not suitable for everybody. Because of this, you will be asked safety questions to help determine if you are able to take part.

Sometimes, MRI scanning for research purposes may not be performed without further investigation if you have a mechanical heart valve or other metallic implants such as an aneurysm clip, hip replacement, or any other pieces of metal that have accidentally entered your body. While there is no evidence to suggest that MRI is harmful to unborn babies, as a precaution, the Department of Health advises against scanning pregnant women unless there is a clinical benefit. If you suffer from claustrophobia, you may not feel comfortable being scanned.

As some of the scans are noisy, we will give you earplugs, or headphones to make this quieter for you. It is important that these are fitted correctly as they are designed to protect your ears. For your comfort and safety we may ask you to change into a gown or a loose pyjama style top and trousers. You may keep your underwear and socks on, but we would ask ladies to remove their bras if they have a wire in (sports bras should be fine). Metal jewellery, including body piercing, must also be removed and if you have any tattoos you will be asked about them in the pre-screening safety questions because some ink types contain materials that can interact with the magnetic field of the MRI scanner. Eye shadow and mascara must also be avoided, since some types contain materials that can interact with the magnetic field. If you wish to wear eye makeup to your scan we can provide makeup removal wipes but you are advised to bring your own makeup to reapply. Lockers are provided to secure your personal belongings and clothing.



During the scan we will use gadolinium based contrast to improve the quality of the MRI images. This is considered safe and is routine in clinical practice, but there are some risks to be aware of. Rarely (fewer than 1 in 100) patients can experience nausea, dizziness headaches or a rash. Very rarely (fewer than 1 in 1000) allergic reactions may occur. The vast majority of gadolinium is rapidly eliminated from the body by the kidneys, but a small amount of gadolinium may remain in the brain, bones and skin for a long time (months to years). The long term effects of this are unknown but no evidence of harm from this exists. In patients with severe kidney impairment very rare complication called “nephrogenic systemic fibrosis” may occur, so we would not include you in this study if we felt you were at risk of this.

Contrast injection: During the CT scan we will use an iodine based contrast agent to help us better see the structures in your body. You may briefly experience a hot flush sensation during the injection of this contrast. The use of iodine based contrast is safe and it will be eliminated from your body by your kidneys. There is however a small risk of an allergic reaction estimated as fewer than 1 in 1000. If you have chronic kidney disease, the use of contrast can cause your kidney function to worsen, so we would not include you in this study if we felt you were at risk of this

Cannulation and blood sampling: Some people find having a cannula a little uncomfortable and there can be bruising at the site of needle entry. Our staff are highly trained in cannulation and will make sure you are as comfortable as possible.

7.What are the possible benefits of taking part?

There is a theoretical possibility that the radiotherapy treatment in this study will reduce your dangerous heart rhythms, but it is likely that there will be no direct benefits from participating in the study. However, the information we gain from this study may help pave the way for a new treatments to prevent dangerous heart rhythms in the future.

8.Will I be reimbursed for taking part?

Travel expenses for study visits will be reimbursed up to a maximum of £30.00 per visit. If you would like us to arrange transport for you please speak to the research team.

9.What happens if you find something unexpected?

In the unlikely event of any unexpected findings of clinical significance on your scans, a clinical specialist will discuss the implications with you and may arrange for further investigations as necessary. However, it is important to note that we do not carry out scans for diagnostic purposes, and therefore these scans are not a substitute for a clinical appointment. Rather, these scans are intended for research purposes only. If we find anything unusual on the scans or tests being carried out in this study, it might be appropriate for us to contact your GP so that they can arrange ongoing clinical care for you. We would only do this after we have discussed your options and gained your permission.

10. Will my General Practitioner (GP) be informed of my participation?

With your consent we will inform your GP about your participation in this study.

11. Will my taking part in the study be kept confidential?

Yes. All study records and samples will be identified only by a code. We will only use names, date of birth and NHS numbers where this is necessary to link to your NHS records or to contact you. Information that can identify you will be held securely by the study team only for the purposes of the study.
Confidentiality will be maintained as far as it is possible, unless you tell us something which implies that you or someone you mention might be in significant danger of harm. In this case, we would have to inform the relevant agencies, but we would discuss it with you first.

Responsible members of the University of Oxford, regulatory authorities and the Oxford University Hospitals NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

12. What will happen to my data?

Your data will be treated the same way irrespective of the outcome of your initial screening assessment. That is, if you exit the study after screening, what follows will still apply.

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly. We will be using information from you and your medical records, NHS Digital and other central NHS registries and will use the minimum personally-identifiable information possible.

Personal information, such as your contact details will be kept by the study Investigators and accessed only by them. All data kept on University computers will be encrypted and password protected. All documents containing personal information such as your informed consent form will be stored securely and only accessible by study staff and authorised personnel in the RDM Division of Cardiovascular Medicine, University of Oxford, at the John Radcliffe Hospital. The study investigator is responsible for keeping these documents securely to ensure that in case of an emergency, participants can be identified and contacted.

We will store any research documents with personal information, such as consent forms, securely at the University of Oxford for 5 years after the end of the study, as part of the research record. If you agree to your samples being used in future research, your consent form will be held until the samples have been depleted or destroyed. If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form until such time as your details are removed from our database but will keep the consent form and your details separate. If a payment is made to cover travel expenses your bank details will be stored for 7 years in accordance with University of Oxford financial policy. We will continue to keep identifiable information about after the study has finished for up to 3 years, to allow time to analyze results, prepare these for publication, and share these results with you if you have indicated you would like this.

Oxford University Hospitals NHS Foundation Trust collects information from you and your medical records for this research study in accordance with our instructions. They will use your name, NHS number and contact details to contact you about the research study, make sure that relevant information about the study is recorded for your care, and oversee the quality of the study. They will keep identifiable information about you from this study – in particular, a copy of the consent form in your medical notes – in keeping with Trust policy for medical notes retention.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

Part of this study will be conducted using commercial equipment (the MR-Linac) owned by the private healthcare provider GenesisCare. Oxford University Hospitals NHS Trust has access to the MR-Linac radiotherapy machine through an institutional agreement with GenesisCare. If you take part in this study some of your data may be transferred to GenesisCare. Only data relevant to the planning and delivery of your radiotherapy treatment will be used. GensisCare have no role in planning or running this research study.

You can find out more about how we use your information by contacting neil.herring@dpag.ox.ac.uk

13. What will happen to the samples I give?

Samples of blood collected will be analysed for this study, but your samples may also be used for other studies with appropriate ethical approval in the future if you give specific consent for this. Samples collected will be stored in secured facilities within the University of Oxford. All data will be identified only by a code number and your identity will remain unknown. Blood samples may be sent to hospitals, universities, non-profit institutions or commercial laboratories worldwide for specialised analyses. If you sign this section of the consent form, you are agreeing to the transfer of samples (along with associated de-identified data) to other countries or centres.

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

You are free to withdraw from the study at any time and for any reason. It will have no effect on your current or future care. If you withdraw from the study, unless you state otherwise, any blood samples which have already been collected whilst you have been in the study will be used for research as detailed in this participant information sheet. You are free to request that your blood samples are destroyed at any time during or after the study. If you choose to withdraw early from this study you will have the following options:

1) You may withdraw from active follow-up and further communication but allow the study team to continue to access your medical records and any relevant hospital data that is recorded as part of routine standard of care; i.e., Remote monitoring of your ICD.

2) You may withdraw from the study but permit data and samples already obtained up until the point of withdrawal to be retained for use in the study analysis. No further data or samples would be collected after withdrawal.

3) You may withdraw completely from the study and withdraw the data and samples collected up until the point of withdrawal. The data and samples already collected would not be used in the final study analysis. However a limitation to this withdrawal would be any samples or data that have already been used as part of interim analysis.

15. What will happen to the results of this study?

We hope that the results will be published in scientific journals and/or presented in scientific or other meetings for the benefit of the wider medical community. However, individual patients will not be identified in any publication or presentation and your personal and clinical details will remain strictly confidential. Any scientific publications arising from the study will be available on request to all participants. You would have no legal right to a share of any profits that may arise from this research. The data from this study may also be used as part of a doctoral thesis.

16. What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact the Chief Investigator Professor Neil Herring. Email: neil.herring@dpag.ox.ac.uk, or you may contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) office on 01865 616480, or the director of RGEA, at rgea.complaints@admin.ox.ac.uk.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

If you wish to contact the PALS team please contact PALS Office, Level 2, main entrance, John Radcliffe Hospital Headley Way, Headington, Oxford OX3 9DU, Tel: 01865 221473, Email: PALS@ouh.nhs.uk
http://www.ouh.nhs.uk/patient-guide/feedback/pals.aspx

17. Who is organising and funding the study?

This study has been designed and organised by Professor Neil Herring, British Heart Foundation Senior Clinical Research Fellow, Associate Professor of Cardiovascular Medicine and Consultant Cardiologist.

This research is being conducted as part of the doctoral thesis of Dr. Benjamin Bussmann, British Heart Foundation Clinical Research and Training Fellow and Cardiology Registrar.

If you wish to know more about any aspect of the study, please contact Professor Herring neil.herring@dpag.ox.ac.uk or Dr Bussmann Ben.bussmann@ouh.nhs.uk

Sponsorship:
This study is sponsored by the University of Oxford.

Funding:
The research is funded by the British Heart Foundation

18. Who has reviewed the study?

All research in the NHS is looked at and checked by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the South Central - Oxford B Research Ethics Committee.

19. Participation in future research:

We will ask if we can contact you about future studies. This is optional, and you can take part in this study but decline to be contacted again about future studies. If you agree, your contact details would be held securely, separately from this study on a password protected computer in the Department of Physiology, Anatomy and Genetics (DPAG) accessible only by research staff from DAPG. You can ask at any time to be removed from this list.

20. Further information and contact details:

If you wish to know more about any aspect of the study, please contact Professor Herring (neil.herring@dpag.ox.ac.uk) or Dr Bussmann (Ben.bussmann@ouh.nhs.uk)

Thank you for considering taking part