

[To be printed on hospital headed paper]



Real-world testing of software for measuring bone disease on whole-body MRI in patients with prostate cancer

We are inviting you to take part in a research study called WISER-P

- Please take time to read the following information carefully. Discuss it with friends/family or GP if you wish.
- Take time to decide whether you would like to take part in this study. The decision is up to you. If you decide not to take part, this will not affect the care you get from your doctors in any way.
- You can decide to stop taking part in the study at any time, without giving a reason.
- Please ask if there is anything that is not clear or if you would like more information.
- Thank you for reading this Information Sheet. If you decide to take part, you will be given a copy of this information sheet for you to keep. You will also be asked to sign a consent form; you'll get a copy of that to keep as well.

Important things that you need to know

Your doctor has informed you that you have prostate cancer that has spread to the bones and has invited you to participate in this clinical trial. Before you decide, it is important for you to understand why the research is being done and what it will involve. Participation is entirely voluntary. If you decide not to take part, your decision will be accepted without question, and your subsequent treatment will not be affected in any way.

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If you have any questions about this clinical trial, please talk to your doctor or nurse. Their details are given on page 6 of the information sheet.

PART 1 – About the WISER-P study

1 What is the purpose of this study?

In advanced prostate cancer, the spread of cancer to bones is common. Recent research has shown that a type of scan, called whole-body magnetic resonance imaging (MRI) (which does not use ionising radiation) may be better than other types of scans at showing cancer in the bones and how well a treatment is working. Whole-body MRI involves a special type of MRI scan, called diffusion-weighted imaging, which provides a measurement of how much bone disease there is in the whole skeleton and more information about what is going on in the cancer cells. The information from the whole-body MRI, along with other clinical assessments, may help doctors decide whether the treatment is working sooner than other types of scans, and change treatment if it is not working. This will help avoid patients remaining on a treatment that is not right for them.

As the whole-body MRI scan provides detailed information about the cancer in the bones it can take a long time for the radiologist to review and analyse the scan. As part of this study, we are assessing an approved (CE marked) imaging software for whole-body MRI. This software is used to automatically identify and measure bone disease on the whole-body MRI and produce a summary report of the scan results to assist the radiologist. This software will reduce the amount of time it takes to analyse the whole-body MRI scan. The summary report may also help the oncology doctors when they review the scan results in clinic.

The aim of this study is to assess the performance of whole-body MRI, with the software, to measure how well treatment is working. This study will also evaluate the whole-body MRI software is for the doctors when they assess the scans and make decisions about treatment.

This study is being run in a few hospitals across the UK. We are aiming to recruit up to 37 patients in total.

2 Why am I being invited to take part in this study?

You have been diagnosed with advanced prostate cancer that has spread to your bones and will shortly be starting a different treatment. As part of your routine care you will need scans prior to starting treatment and again during treatment to see how well it is working. Therefore, your doctor feels you are suitable for this study and you are being invited to take part.

3 What will happen to me if I take part?

Prior to being invited to take part in this study, and as part of your routine care, you will already have had scans to assess your cancer, including that in your bones. A decision has been made that you will soon start a different treatment. Your planned treatment will not change if you take part in this study. Please discuss any questions about this with the doctor looking after you.

After you have given consent you will have a whole-body MRI scan before you start treatment and again, between 8 and 12 weeks after you start treatment. Apart from these scans, all other clinical assessments such as bloods tests, will be performed as part of your routine care and will not change if you take part in this study. You will be seen regularly by your doctor.

If you have already had a whole-body MRI scan as part of your routine care within 6 weeks of your planned date for starting treatment, then this will not need to be repeated as part of the study. And you may be invited to take part in the study after you have started treatment but before your first follow-up scan. If so, and once you have given consent, you will then have one further whole-body MRI scan as part of the study, between 8 and 12 weeks after you started treatment.

We will also collect information from your hospital on how you are doing on one further occasion, once all participants have been recruited to the trial and completed the scans. You will not need an extra visit to the hospital for this as the information we collect as part of the study will already be available within your medical records.

A summary of what a whole-body MRI scan involves is given below. As these types of scans are already performed at your hospital as part of routine care you will likely receive more information about these directly from your hospital prior to your scan appointments.

What does a whole-body MRI scan involve?

An MRI scan uses magnetism and radio waves to take pictures of inside the body. An MRI scanner is shaped like a long tube as shown in the picture below.

During the scan you will be asked to lie down on a scanner couch. MRI coils, which are shown in the picture below, are then placed over your body, from your head down to your thigh. The head coil includes a mirror that allows you to see a view towards your feet and outside of the scanner. Once the coils are in place the scanner couch moves through the scanner. As the scan can be very noisy you will be asked to wear headphones. Towards the end of the scan, you will be asked to hold your breath for up to 20 seconds. The number of breath holds will depend on the particular scanner used at your hospital. These instructions will be relayed to you via the headphones and the radiographer performing the scan will keep in touch with you throughout the scan. You will be asked to lie as still as possible during the scan, which normally takes about 40 minutes.



MRI scanner



Lightweight coils are placed over
your body during a whole-body
MRI scan

4 How to decide whether to take part in this study?

What are the benefits of taking part in this study?

All patients in the study will have a whole-body MRI scan to find out how well treatment is working, and these types of scans are already widely used to diagnose and monitor patients with cancer. The information we get from this study will help us assess whole-body MRI, and software, for measuring how well treatment is working in patients with advanced prostate cancer involving the bones. Although you may not directly benefit by taking part in the study, it will help to answer important questions, and will improve how we assess response to treatment in men with advanced prostate cancer in the future.

What are the possible disadvantages and risks of taking part in this study?

Because of your participation in the study, you will need to visit the hospital to have a whole-body scan prior to starting treatment (unless you have had a recent whole-body MRI scan as part of your routine care). The number of hospital visits after this will be the same whether or not you participate in the study.

Whole-body MRI is a safe and painless procedure and is not associated with any ionising radiation exposure. There is no evidence that the magnetic fields and radio waves used during MRI scans cause any harm to your body. Although there is no radiation exposure with MRI scans, the procedure involves you keeping still whilst on the scanner table for the duration of the scan. You will be made as comfortable as possible before you start but it is noisy and you will be in a narrow tunnel. During

the whole-body MRI scan you may feel the scanner table vibrate. This is normal and expected. Some patients may feel claustrophobic and may experience discomfort related to lying still in an enclosed space for a prolonged period while the scan is being taken. The radiographer performing the scans will ensure you are as comfortable as possible before starting the scan.

Do I have to take part in the study?

No, you do not have to take part; it is up to you to decide. If you do decide to take part, you will be asked to sign a consent form. You are also free to withdraw at any time and without giving a reason. Should you withdraw, this will not affect the standard of care you receive. However, if you did decide to withdraw, we would like your permission please to keep the information we have already collected from you and to collect information on your progress, available within your medical records, on one further occasion once all participants have been recruited to the study and had their follow-up scan.

What if there is a problem or I have a complaint?

Any complaint about the way you have been dealt with during this study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2 of this information sheet.

Will my participation in the study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2 of this information sheet.

Contact Details

If, at any time, you have any questions about the study you should contact your hospital team:

Local Consultants name: Address, Telephone, E-mail [details to add]

Local Nurse name: Address, Telephone, E-mail [details to add]

24 Hour Contact Number, 7 days a week [details to add]

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

PART 2 – General Information

1 WB-MRI Scans

We will ask your hospital to upload a copy of your whole-body MRI scans performed during the study to a secure image storage system at The Institute of Cancer Research. Your scans will be labelled with your initials and unique study ID when they are uploaded to maintain your confidentiality. The scans will be stored indefinitely and strictly in accordance with national guidelines.

You are asked to give permission for possible future research using these scans; this may involve your scans being sent to institutions outside the UK and the European Economic Area. It may be necessary to include commercial companies involved in imaging software development. For example, in situations where the research organisations do not have access to the resources needed to carry out the research associated with optimising software within a short time frame. This will include the company Mint Medical GmbH, which worked in collaboration with the researchers, to develop the imaging software for whole-body MRI being used in this study. The confidential nature of these scans and associated data will be fully protected, and any other research using your scans will first be reviewed and approved by an ethics committee.

2 Confidentiality

How will we use information about you?

We will need to use information from you and your medical records for this research project.

This information will include your:

- Postcode
- Initials
- Date of birth
- Ethnicity
- Current health
- Cancer diagnosis and treatment
- Blood tests results taken during your treatment
- Scan results

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

The Institute of Cancer Research (ICR) is the sponsor of this research, and is responsible for looking after your information. The ICR's lawful basis for processing your information is for the performance of a task carried out in the public interest and we process special category information for the purpose of scientific research. We will keep all information about you safe and secure by:

- using a unique study identifier number allocated to you to link all the scans and data that you provide.
- storing all your information and scans securely.

- treating your information and samples as strictly confidential and nothing that might identify you will be revealed to any third party.
- using the minimum personally-identifiable information possible.
- limiting access to your information to only those who need to use it for research or regulatory reasons and regularly reviewing who has access to your information.
- using strong encryption anytime we need to share your information.
- ensuring everyone who has access to your information has been trained on how to use it in a safe way.
- keeping our Data Protection Officer informed on how we use personal data so they can advise us on how to keep your information safe.

International transfers

We may share data about you outside the UK for research related purposes to:

- optimising whole-body MRI and associated software for use in patients with cancer.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Research institutions including universities and hospitals
- Companies involved in healthcare research and development

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details [visit the Information Commissioner's Office \(ICO\) website](#)
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules [visit the Information Commissioner's Office \(ICO\) website](#)

Once we have finished the study, we will keep some of the data so we can check the results. 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 for a maximum of **20** years. The study data will then be fully anonymised and securely archived or destroyed.

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. If you do not want this to happen, tell us and we will stop.
- You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- 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. All scans will be stored on a central image repository called XNAT.

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

- our leaflet: www.hra.nhs.uk/patientdataandresearch
- our privacy notice on our website: www.icr.ac.uk/legal/privacy/research-privacy-notice
- by sending an email to our Data Protection Officer: dataprotectionofficer@icr.ac.uk
- by asking one of the research team, or
- by ringing our Data Protection Officer on 020 3437 7327.

3 Further information

What if something goes wrong?

It is unlikely that anything will go wrong with your treatment or care, but if you wish to complain about any aspect of the way you have been treated during the course of the study you can do so using the normal NHS complaints procedure. The link below should help you gather further information about how to make a complaint.

<https://www.nhs.uk/using-the-nhs/about-the-nhs/how-to-complain-to-the-nhs/>

Healthcare professionals working on Clinical Trials are covered by NHS Indemnity and if you are harmed by taking part in this study you may have grounds for legal action but you may have to pay for it. The Sponsor of this trial holds a clinical trials insurance policy.

If you do wish to complain about any aspect of the way you have been approached or treated during this study, the normal National Health Service complaints mechanisms are available to you. Concerns should be raised by speaking to a member of staff at your hospital or by talking to the local Patient Advice and Liaison Service (PALS), or equivalent in devolved nations, which has been established in every NHS Trust and Primary Care Trust (PCT).

What happens if I don't want to carry on with the study?

You are free to withdraw from the study at any time. You do not have to give a reason, and your future treatment will not be affected.

However, if you were to withdraw, we would like your permission to keep the information we have already collected from you and to collect information on your progress, available within your hospital records, on one further occasion once all participants have been recruited to the study and had their follow-up scan. This is so that the overall quality of the study is not impaired and enough information is collected to answer the main aim of the trial.

If you decide you want to stop participation and do not want any more information to be sent to the research centre, trial data collected before your decision will still be processed along with other data collected as part of the study, however no new data will be added to the study database.

What will happen to the results of the research study?

Independent experts will review the progress of the research, and the results will be published in a medical or scientific journal as soon as there is enough information to be sure the results are reliable. You will not be identified in any report or publication. The results will help to decide how to manage patients with prostate cancer in the future. The results of this study are not likely to be available for at least 3 years. If deemed appropriate at the time that the results are available, your hospital will write to you when the results are known to ask if you or a family member would like to see them. The letter will explain how to get a copy.

Who is organising and funding the research?

The research study is being carried out by a network of doctors across the UK. The trial is co-ordinated by the Institute of Cancer Research. The research is funded by the National Institute for Health Research in the UK.

Your doctor will not receive any payments for including you in this research study. You will not be paid for taking part in this study, but some hospitals may be able to help arrange hospital transport for your hospital visits. Please check with your doctor if this is available at your hospital.

Who has reviewed the study?

WISER-P has been approved by the North East Newcastle and North Tyneside 2 Research Ethics Committee, the Sponsor Committee for Clinical Research (CCR) and Health Research Authority.

What do I have to do now?

You will have some time to think about the study and make your decision. You may wish to discuss it with your family or friends. Please keep this information sheet and copies of the signed consent form. If, at any time, you have any questions about the study you should contact your consultant.

4 Contacts for support

You can learn more about clinical trials on the Cancer Research UK's patient website (www.cancerhelp.org.uk).

Further information: Macmillan Cancer Support is a registered charity providing information, emotional support and publications about all aspects of cancer for cancer patients and their families. You can contact one of their Cancer Information Nurse Specialists on the Macmillan Support Line; Freephone 0808 808 00 00, Monday to Friday, 9.00am to 8.00pm. In addition to their nurses, the Macmillan Support Line also has other specialist teams that can provide advice and information relating to welfare benefits, financial issues and everyday practical concerns.

Thank you for interest in our research.

TO BE PRINTED ON HOSPITAL HEADED PAPER

WISER-P Consent Form

Version 3.0, Dated XX XXX 2025

REC Reference: 23/NE/0034

IRAS project ID: 315173

CCR Number: CCR5680

Patient's hospital number:

WISER-P Study ID:

Please write your initials in the box to the right of each statement if you agree, and please sign and date at the bottom of the form

Items 1-7 are required for your participation in WISER-P		Initials
1.	I confirm that I have read and understood the WISER-P PATIENT INFORMATION SHEET, Version 3.0, dated 30 April 2025 and have had the opportunity to ask questions and had these answered satisfactorily.	
2.	I agree to take part and be registered into the WISER-P study. 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.	
3.	I agree to my initials, date of birth, and post code, number being sent to The Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU) when I join WISER-P.	
4.	I agree to ICR-CTSU using NHS to collect information on my health status.	
6.	I understand that sections of my medical records may be examined by representatives from the ICR-CTSU, the NHS Trust relevant to my taking part in research, the Sponsor (The Institute of Cancer Research), the regulatory authorities and ethics committee approving the study, and third parties approved by ICR-CTSU to the extent permitted by applicable laws and regulations to make sure the information received is correct. I give permission for these individuals to have access to my records.	
7.	I agree to take part in the WISER-P Study	

OPTIONAL CONSENT

Please initial to indicate whether you wish to consent to the following optional items

