[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 explained to 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. Currently the most widely used scans to find out if cancer has spread to the bones are bone scans and computed tomography (CT). These scans are also used to find out how well treatment for advanced prostate cancer is working.

Recent research has shown that a different type of scan, called whole-body magnetic resonance imaging (MRI) may be better 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. This more detailed information cannot be obtained using a CT scan or bone scan. It has been shown that it may be possible to assess whether treatment is working more quickly using whole-body MRI compared to bone scans and CT scans. The information from the whole-body MRI, along with other clinical assessments, may help doctors decide whether the treatment is working sooner and change it 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 also assessing an approved imaging software for whole-body MRI. This software is used to automatically identify and measures bone disease on the whole-body MRI and produce a summary report of the scan results. 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 find out whether whole-body MRI is better at finding out how well a treatment is working compared with bone and CT scans. This study will also evaluate the whole-body MRI software to find out how useful this is for the doctors when they assess the scans and make decisions about treatment.

This study is being run in a number of hospitals across the UK. We are aiming to recruit up to 126 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.

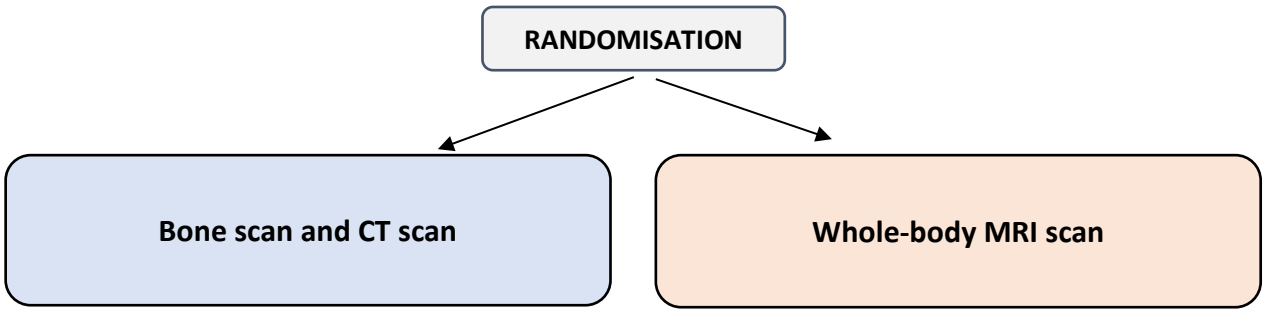
3 What will happen to me if I take part?

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 to that you were receiving before. 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 either bone and CT scans or a whole-body MRI scan before you start treatment. These scans will then be repeated approximately 8-9 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. We will collect information from your hospital on how you are doing at your routine follow-up visits up to 12 months after you start your planned treatment.

Half of the participants in the study will receive bone and CT scans and the other half of patients will receive whole-body MRI scans. In some cases, and as part of routine care, an MRI scan of the pelvis may be performed instead of or as well as the CT scan, and this would be allowed if you take part in the study.

The choice of which type of scan you have is made randomly (by a computer) at the time you enter the study and is the equivalent of tossing a coin. This process is called randomisation. This is the best way to make sure that the patients in each group are as similar as possible. Then, if the scans in one group are shown to be better than those in the other group, it is more likely to be because of the scans themselves, rather than because the patients in one group are somehow different from those in the other groups.



A summary of what each of the scans involves is given below. As all the scans in this study are already performed at your hospital as part of routine care you will receive more information about these directly from your hospital prior to your scan appointments. You are likely to have had some of these scans at the time your cancer was diagnosed and during your treatment.

If you are randomised to the group that receives a bone scan and a CT scan, and these have already been performed as part of your routine care within 6 weeks of your planned date for starting treatment, then these will not need to be repeated.

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

What does a Bone Scan involve?

A bone scan looks for changes in your bones. You will be asked to drink plenty of fluids before and after the scan. A small amount of a safe radioactive liquid, called a tracer, will be injected into a vein in your arm. You will have the scan two to three hours later allowing time for the tracer to go around the body and collect in your bones. During the scan, you will lie on a scanner couch which slowly moves through the scanner taking pictures of your bones. You will be asked to lie as still as possible during the scan, which will take between 30 minutes to an hour. Your body gets rid of the radioactive tracer through the urine, usually within 24 hours.

What does a CT scan involve?

A CT (computerised tomography) scan uses x-rays and a computer to create detailed pictures of the inside of your body. Before the scan of your chest, abdomen and pelvis you might have an injection of a type of dye called a 'contrast medium' through a vein in your arm. Your hospital will provide more information about this. During the scan you will lie down on the scanner couch, which will then slowly move back and forth through the hole of the scanner. You will be asked to lie as still as possible during the scan, which normally takes between 20 and 30 minutes.

Will I be asked to do anything else?

In addition to the scans described above you will also be asked to take part in an optional patient reported outcome sub-study. If you decide to take part, you will be provided with a patient reported outcomes booklet. This booklet includes questions about your general health and how your diagnosis and treatment effects your daily life.

You will be asked to complete this booklet before you start treatment, and again at 8-9 weeks and 12 months after you start treatment. The questionnaire is optional and you can still take part in the main study if you do not consent to this sub-study.

The booklet is split into two sections:

Quality of life: A short questionnaire asking about your quality of life and general health.

Health Resource Use: A questionnaire about how your treatment for cancer affects your daily life. This includes questions about any help or support you are receiving, healthcare visits such as appointments with your GP and any expenses associated with your health and treatment. You will only need to answer these questions at the time you have your scan(s) at 8-9 weeks after starting treatment and again at 12 months after starting treatment.

A member of your medical team will explain these questionnaires to you and answer any questions that you may have. The questionnaire should take about 10 minutes to complete.

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 scans 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 find out if whole-body MRI is better at showing how well a treatment is working compared with bone and CT scans 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 we hope will improve treatment for 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 scan (or scans) prior to starting treatment. The number of hospital visits after this will be the same whether or not you participate in the study.

If you take part in this study, you could have CT scans and bone scans. Some of these could be extra to those that you would have if you did not take part. These procedures use ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure. In patients with your current clinical condition, the chance of this happening to you is extremely small.

Whole-body MRI is a safe and painless procedure and is not associated with any 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 can be noisy and you will be in a narrower tunnel than for a CT. 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 of time 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 continue to collect information on your progress that will be routinely recorded in your medical records up to 12 months after you start treatment.

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 Scans

We will ask your hospital to upload a copy of your 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

Who will have access to my data?

The Institute of Cancer Research is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The Institute of Cancer Research will keep identifiable information about you for at least 5 years after the study has finished.

The Institute of Cancer Research's lawful basis for processing your information is for the performance of a task carried out in the public interest and it is necessary to process sensitive health and genetic information for the purposes of scientific research with appropriate safeguards in place to protect personal information, as required by the United Kingdom General Data Protection Regulation (UKGDPR).

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit/transparency.

[Insert appropriate name for NHS site] will collect information from you and your medical records for this research study in accordance with our instructions.

[Insert appropriate name for NHS site] will use your full name, hospital number, date of birth, postcode and NHS number (or Community Health Index (CHI) and/or hospital number in Scotland) to

contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

Will my taking part in this study be kept confidential?

All information which is collected about you during the study will be kept strictly confidential. When you join the trial, your full name, hospital number, date of birth, postcode and NHS/CHI number will be passed to The Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU) where the study is being coordinated. You will be given a unique trial ID number, which will be used together with your initials and date of birth on forms that the research staff at your hospital will send to ICR-CTSU. All information about you will be stored securely. It will be treated as strictly confidential and nothing that might identify you will be revealed to any third party. Only members of the research teams at your hospital and the ICR-CTSU will have access to the information that could allow this trial ID number to be linked to you.

Representatives from the ICR-CTSU, the NHS Trust relevant to your taking part in research, and ethics committee approving the trial and third parties approved by ICR-CTSU may need to see your hospital or clinic records to the extent permitted by applicable laws and regulations to make sure the information received is correct. All information will be kept confidential.

[Insert appropriate name for NHS site] will keep identifiable information about you from this study for at least 5 years after the study has finished.

Will information about me be shared with other researchers?

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations now or in the future. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government. Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

Where can I find out more about how my information is used?

You can find out more about how we use your information or your rights:

- at https://www.icr.ac.uk/legal/privacy
- by sending an email to ICR's Data Protection Officer at dataprotectionofficer@icr.ac.uk

- at www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit/transparency
- at www.hra.nhs.uk/information-about-patients

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, delete/complete as appropriate]* 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 continue to collect information on your progress that is routinely recorded in your medical records up to 12 months after you start treatment. 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 2.0, Dated 27 March 2023

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 2.0, dated 27 March 2023** 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, full name, date of birth, post code, hospital number and NHS or Community Health Index (CHI) 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 and national health and registration data to collect information on my health status.	
5.	I agree to researchers from The Institute of Cancer Research linking my NHS number to national databases in order to collect information relating to hospital visits and hospital activity.	
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

		INITIALS	
		YES	NO
8.	If I withdraw from the study, I consent to my doctor providing authorised researchers with basic clinical information that would be routinely collected and written in my medical records.		
Patient-reported outcome questionnaire sub-study			
9.	I consent to take part in the patient-reported outcomes questionnaire sub-study as described in the information sheet and I understand that the information I provide in the questionnaires, including my full address, will be sent to the Clinical Trials and Statistics Unit at the Institute of Cancer Research.		
Data Sharing			
10.	I grant advance authorisation for the possible future sharing of information collected about me, including any imaging (relating to my cancer), with other organisations, including those outside of the UK and European Economic Area (EEA) with the understanding that I will not be identifiable from this information.		

_____	_____	_____
Name of Patient	Signature	Date
_____	_____	_____
Name of Clinician	Signature	Date

Please note, one copy of the patient information sheet and signed consent form should be given to the patient, one copy should be retained in the Site Investigator File and one copy should be filed in the patient's medical records.