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Using software to measure bone disease on imaging for patients with prostate cancer

Submission date
20/07/2023

Recruitment status
Recruiting

Registration date
12/10/2023

Overall study status
Ongoing

Last Edited
30/06/2025

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
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 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.

Who can participate?
This study is for people over the age of 18 who have been diagnosed with advanced prostate cancer that has spread to the bones and who will shortly be starting a different treatment.

What does the study involve?
The patient will already have had scans to assess your cancer as part of routine care. A decision

has been made that the patient will soon start a different treatment. The planned treatment will not change if the patient takes part in this study.
After consent is given, the patient will have a whole-body MRI scan before starting treatment and again, between 8 and 12 weeks after starting treatment. Apart from these scans, all other clinical assessments such as bloods tests, will be performed as part of routine care and will not change as a result of taking part in this study.
Patients who have already had a whole-body MRI scan as part of routine care within 6 weeks of the planned date for starting treatment, will not need to be repeated as part of the study and may be invited to take part in the study after starting treatment but before first follow-up scan. If so, and once consent has been given, these patients will then have one further whole-body MRI scan as part of the study, between 8 and 12 weeks after starting treatment.
Information will be collected from the patient's hospital on how they are doing are doing on one further occasion, once all participants have been recruited to the trial and completed the scans. This will not require an extra visit to the hospital for this as the information we collect as part of the study will already be available within medical records.

What are the possible benefits and risks of participating?
Benefits-
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 patients 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.

Disadvantages and Risks-
Patients will need to visit the hospital to have a whole-body scan prior to starting treatment (unless have had a recent whole-body MRI scan as part of routine care). The number of hospital visits after this will be the same whether or not patients 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 the body. Although there is no radiation exposure with MRI scans, the procedure involves patients keeping still whilst on the scanner table for the duration of the scan. Patients 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 patients 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 patients are as comfortable as possible before starting the scan.

Where is the study run from?
The Institute of Cancer Research Clinical Trials and Statistics Unit, London (UK)

When is the study starting and how long is it expected to run for?
September 2020 to November 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Christophe Verstegen, wiser-icrctsu@icr.ac.uk

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-whole-body-mri-scans-for-prostate-cancer-that-has-spread-to-the-bones-wiser-p

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
315173

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 55351, IRAS 315173

Study information

Scientific Title
WISER-P: Real-world testing of software for measuring bone disease on whole-body MRI in patients with prostate cancer

Acronym
WISER-P

Study objectives
Current study hypothesis as of 30/06/2025:

WBMRI will shorten time to treatment discontinuation as progression in bone disease at 8-12 weeks from start of therapy can be detected more confidently with WBMRI than with conventional imaging. With the latter, radiological progression (e.g. as per PCWG3 criteria)

cannot be defined as confidently and, therefore, the patient may remain on ineffective treatment for longer.

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Previous study hypothesis:

WB-MRI will shorten time to treatment discontinuation as progression in bone disease at 8-9 weeks from start of therapy can be detected more confidently with WBMRI than with CT/bone scan. With the latter, radiological progression (e.g. as per PCWG3 criteria) cannot be defined as confidently and, therefore, the patient may remain on ineffective treatment for longer

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/04/2023, North East - Newcastle & North Tyneside 2 Research Ethics Committee (NHS BT Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 207 104 8016; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 23/NE/0034

Study design
Multicentre prospective single arm design

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
Current interventions as of 30/06/2025:

All patients will undergo WBMRI prior to commencement of systemic treatment and again at 8-12 weeks with target of 8-9 weeks from start of treatment to align with PCWG3 guidelines. Following this 1st on-treatment scan, both this and the baseline WBMRI scan will be uploaded to a cloud-hosted imaging platform and the test whole-body MRI software applied for automated identification and segmentation of bone disease, and subsequent generation of a software output with highlighted areas of bone disease and cellular characteristics including TDV and ADV values. This output will be used by site radiologists as an adjunct to conventional qualitative image assessment of WBMRI for radiology reporting. Both the text-based report and software output will be available for review by the treating clinician, together with all other clinical evidence available at this time-point for decision making around treatment continuation or discontinuation. Radiological assessment afterwards will be as per local practice, and/or as clinically indicated. Clinical and laboratory assessments including disease symptoms, will be according to local practice and as clinically indicated.
Disease and survival status will be assessed for all patients 3 months after last patient last on-trial WBMRI scan using information available within electronic patient records.

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Previous interventions:

Patients will be randomised, using a 1:1 ratio, to a WBMRI (and associated software) pathway or conventional imaging pathway (bone scan plus CT as per local practice).

All patients will undergo imaging, according to randomised group, prior to commencement of planned systemic treatment and again at 8-9 (± 1 week) weeks from start of treatment as per Prostate Cancer Working Group 3 guidelines.

Radiological assessment afterwards will be as per local practice, and/or as clinically indicated. Clinical and laboratory assessments including disease symptoms, will be according to local practice and as clinically indicated.
Patients will be followed up for 12 months from start of treatment to assess survival status. At this point, treatment discontinuation and other disease outcomes will be assessed from patient notes as per normal practice for both pathways.

Quality of life will be assessed at baseline, at the time of the first on-treatment imaging at 8-9 weeks and at 12 months using EQ-5D-5L. Healthcare resource use questionnaires will also be completed at 8-9 weeks and 12 months to assess cost-effectiveness of WBMRI.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Current primary outcome measure as of 30/06/2025:

1. The proportion of patients with evidence of radiological progression as assessed using the 8-12 weeks WBMRI after start of treatment supported with software reporting.

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Previous primary outcome measure:

1. Number of patients with evidence of radiological progression as assessed in the first on-treatment imaging performed at 8-9 weeks after start of treatment.
2. Number of patients for whom decision is made to discontinue treatment due to disease progression following the first on-treatment imaging (8-9 weeks) and before start of subsequent cycle, taking into account imaging and all other available evidence.

Key secondary outcome(s))
Current secondary outcome measures as of 30/06/2025:

1. Proportion of patients with radiological response using the 8-12 weeks WBMRI with software reporting.
2. Proportion of patients for whom decision is made to discontinue treatment due to disease progression following the 8-12 week WBMRI with software reporting, taking into account imaging and all other available evidence.

3. Clinician’s confidence in clinical decision making (continue/discontinue treatment) following the 8-12 weeks WBMRI with software reporting.
4. Proportion of patients who respond to treatment according to the clinician perspective following the 8-12 week WBMRI scan.
5. Time to treatment discontinuation and reason(s) for treatment discontinuation.
6. Radiological progression free survival (rPFS), progression free survival (PFS)
7. Association between time to radiological progression and time to PSA progression.

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Previous secondary outcome measures:

1. Clinician’s confidence in clinical decision making (continue/discontinue treatment) after first on-treatment scan (8-9 weeks from start of therapy).
2. Proportion of patients who respond to treatment according to clinician perspective at the first on-treatment imaging (8-9 weeks from start of treatment)
3. Time to treatment discontinuation and the specific reason(s) a therapy was ultimately discontinued measured using patient records
4. Health-related quality of life (using EQ-5D-5L) at baseline, at first on-treatment scan (8-9 weeks) and 12 months from start of treatment.
5. Overall survival at 12 months measured using patient records
6. Radiological Progression Free Survival (rPFS) and Progression Free Survival (PFS) measured using patient records
7. Time to radiological progression and time to PSA progression measured using patient records
8. In the WBMRI group, proportion of patients with radiological response measured using patient records
9. Health economic evaluation with budget impact and cost-effectiveness of WBMRI

Completion date
30/11/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 30/06/2025:

1. Age ≥ 18 years.
2. Metastatic castration-resistant prostate cancer with bone-predominant disease confirmed on bone scan, CT, or limited (pelvic) MRI performed within 8 weeks prior to trial entry (bone-predominant disease confirmed on the CT component of PET-CT is permissible).
Or for patients who have already had a WBMRI performed within 6 weeks of starting therapy and are to be enrolled onto the trial after they have started treatment: bone -predominant disease confirmed on bone scan, CT, or limited (pelvic) MRI performed within 8 weeks prior to start of treatment (bone-predominant disease confirmed on the CT component of PET-CT is permissible).
2.3. Systemic therapy (any line) clinically indicated and planned (or already started*) for treatment of disease progression, as defined and confirmed locally with potential definitions including but not limited to:
• Progression on bone scan: ≥ 2 new documented bone lesions over the previous 6 months
• AND/OR increasing PSA level: 2 consecutive increases in PSA level documented over a previous reference value obtained at least one week apart. If the third PSA value is less than the second,

an additional fourth test to confirm the rising PSA is required.
3.4. Willing and able to comply with the protocol defined imaging assessments.
4.5. Fully informed about the study and provided written informed consent.

* For patient who have already had a WBMRI as part of their routine care within 6 weeks of starting therapy and are to be enrolled into the trial after they have started treatment prior to the protocol-defined 8-12 week scan.

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Previous inclusion criteria:

1. Age > = 18 years.
2. Metastatic castration-resistant prostate cancer with bone-predominant disease confirmed on bone scan, CT, or limited (pelvic) MRI performed within 8 weeks prior to trial entry (bone-predominant disease confirmed on the CT component of PET-CT is permissible).
3. Systemic therapy (any line) clinically indicated and planned for the treatment of disease progression, as defined and confirmed locally with potential definitions including but not limited to:
3.1. Progression on a bone scan: > = 2 new documented bone lesions over the previous 6 months
3.2. AND/OR increasing PSA level: 2 consecutive increases in PSA level documented over a previous reference value obtained at least one week apart. If the third PSA value is less than the second, an additional fourth test to confirm the rising PSA is required.
4. Willing and able to comply with the protocol-defined imaging assessments.
5. Fully informed about the study and provided written informed consent.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
1. Unsuitable for WBMRI (patient refusal and/or contraindicated)
2. Patients with RECIST-measurable disease
3. Any radiotherapy within 8 weeks prior to trial entry (chemotherapy or other anti-cancer therapy are permissible).

Date of first enrolment
01/09/2023

Date of final enrolment

01/09/2026

Locations

Countries of recruitment
United Kingdom

Study participating centre
The Royal Marsden Hospital (surrey)
Downs Road
Sutton
United Kingdom
SM2 5PT

Sponsor information

Organisation
Institute of Cancer Research

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Wiser-icrctsu@icr.ac.uk and via a standard proforma describing the nature of the proposed research and extent of data requirements. Data recipients are required to enter a formal data sharing agreement that describes the conditions for release and requirements for data transfer, storage, archiving, publication, and intellectual property. Requests are reviewed by the Trial Management Group (TMG) in terms of scientific merit and ethical considerations including patient consent. Data sharing is undertaken if proposed projects have a sound scientific or patient benefit rationale as agreed by the TMG and approved by the Independent Advisory Group (IAG) as required. Restrictions relating to patient confidentiality and consent will be limited by aggregating and anonymising identifiable patient data. Additionally, all indirect identifiers that could lead to deductive disclosures will be removed. Generally, data access requests will be considered only after the publication of the principal analysis of the primary endpoint.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes