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WISER-M: Developing software to measure bone disease on imaging for patients with multiple myeloma

Submission date 12/07/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 09/10/2024	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 08/09/2026	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

In multiple myeloma, NICE recommends whole-body MRI for diagnostic staging. However, a survey showed that only 10% of NHS sites use whole-body MRI, despite it being more accurate and more cost-effective. There are a number of reasons for this, including a lack of expertise to perform this type of scan and interpret the images, and a lack of software for whole-body MRI analysis. Where used, whole-body MRI scans are reviewed visually by radiologists, who will then produce a text-based report. This is limited because there can be variation in image interpretation by different radiologists, review time can be long and qualitative descriptions (such as small vs. large volume) can be imprecise. Through previous NIHR funding, together with a commercial partner, a CE-labelled software for the identification and quantification of bone disease has been developed for use in patients with metastatic prostate cancer. This software may also have a role in detecting and measuring bone disease in patients with suspected myeloma, requiring the development and validation of a myeloma-specific software algorithm.
The WISER-M study involves the retrospective collection of whole-body MR scans and limited patient data, previously acquired as part of routine care and available via electronic patient records. It has two main objectives:
1. to develop and internally validate a myeloma-specific algorithm with optimal diagnostic performance to detect and measure bone disease on whole-body MRI in patients with active focal disease associated with multiple myeloma via a single-centre retrospective study (Training /Internal Validation cohort, n=200 cases)
2. to externally validate the diagnostic performance of the algorithm as measured by its per-lesion sensitivity to detect focal lesions in newly diagnosed myeloma cases via a multi-centre retrospective study (External Validation cohort, n=60 cases).
WISER-M also includes a sub-study to evaluate clinical usability to provide preliminary evidence to inform future trials
testing a validated myeloma-specific algorithm.

Who can participate?

This study is for patients with confirmed multiple myeloma who underwent a WBMRI scan as standard of care during their diagnostic (Training/Internal Validation & External Validation

Cohorts) and/or treatment (Training/Internal Validation Cohort only) pathway, within the preceding 8 years.

What does the study involve?
WISER-M is limited to retrospective collection of routinely acquired scans and data available within electronic patient records. The WISER-M study team will receive de-identified data only. Local NHS site teams will be responsible for pseudo-anonymisation of WBMRI and patient data prior to transfer to the central image repository and study database, respectively. Eligible patients will be identified via electronic patient records by the site team, and each patient identified will be assigned a unique Study ID.

What are the possible benefits and risks of participating?
Benefits and risks not provided at time of registration

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

When is the study starting and how long is it expected to run for?
October 2023 to November 2026

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

Who is the main contact?
Dr Natasha Iles, wiser-icrctsu@icr.ac.uk
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Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
315705

Central Portfolio Management System (CPMS)
57925

National Institute for Health and Care Research (NIHR)
202161

Study information

Scientific Title
Development and validation of an algorithm to detect and measure bone disease on whole-body MRI in patients with multiple myeloma

Acronym
WISER-M

Study objectives
Current study objectives as of 15/06/2026:

1. To develop and internally validate a myeloma-specific algorithm with optimal diagnostic performance to detect and measure bone disease on whole-body MRI in patients with active focal disease associated with multiple myeloma via a single-centre retrospective study (Training /Internal Validation cohort, n=200 cases)
2. To externally validate the diagnostic performance of the algorithm as measured by its per-lesion sensitivity to detect focal lesions in newly diagnosed myeloma cases via a multi-centre retrospective study (External Validation cohort, n=60 cases).
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Previous study objectives:

1. To develop and internally validate a myeloma-specific algorithm with optimal diagnostic performance to detect and measure bone disease on whole-body MRI in patients with active focal disease associated with multiple myeloma via a single-centre retrospective study (Training

/Internal Validation cohort, n=100 cases)
2. To externally validate the diagnostic performance of the algorithm as measured by its per-lesion sensitivity to detect focal lesions in newly diagnosed myeloma cases via a multi-centre retrospective study (External Validation cohort, n=60 cases).
WISER-M also includes a sub-study to evaluate clinical usability to provide preliminary evidence to inform future trials testing a validated myeloma-specific algorithm

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/06/2024, West of Scotland REC 5, West of Scotland Research Ethics Service (Ward 11, Dykebar Hospital Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 141 314 0213; WoSREC5@ggc.scot.nhs.uk), ref: 24/WS/0076

Primary study design
Observational

Study design
Observational cohort study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Multiple myeloma

Interventions
Current methodology as of 15/06/2026:

WISER-M is a multi-centre, multi-cohort retrospective study involving collection and analyses of routinely acquired whole-body MRI scans and clinical diagnostic and clinical outcome data in patients with myeloma to develop and validate an algorithm for automated detection and measurement of bone disease on whole-body MRI, including:

A. Single-centre retrospective study (Training/Internal Validation cohort): Retrospective collection and analysis of whole-body MRI scans and limited diagnostic clinical, laboratory and pathology data from a single UK site for training of a whole-body MRI algorithm for detecting and measuring bone disease in patients with active focal disease associated with myeloma – Royal Marsden Hospital (n=200)

B. Multi-centre retrospective study (External Validation cohort): Retrospective collection and analysis of whole-body MRI scans from up to 6 UK sites excluding Royal Marsden Hospital for validation of the whole-body MRI algorithm for detecting and measuring bone disease in patients with newly diagnosed myeloma (n=60)

C. Clinical Usability Sub-study: clinical review of up to 20 case studies from the Training Cohort to evaluate clinical usability of the software. This will provide preliminary evidence to inform design of future real-world testing of a validated myeloma-specific algorithm.

For newly diagnosed cases included in (A) and (B) the following clinical, laboratory and pathology data routinely acquired during the patient's diagnostic and treatment pathway, and available within electronic patient records, will be collected:
1. Date of confirmed diagnosis of myeloma
2. Laboratory markers of disease burden (blood and urinary tumour markers, bone marrow biopsy)
3. Molecular subtype and other molecular characteristics if available
4. Patient management recommendations including treatment and follow-up schedule following confirmed diagnosis and prior to start of treatment pathway
5. Clinical outcome data including serological response to treatment, assessment of minimal residual disease if performed locally, and survival status if known

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C. Clinical Usability Sub-study: clinical review of up to 20 case studies from the Training Cohort to evaluate clinical usability of the software. This will provide preliminary evidence to inform design of future real-world testing of a validated myeloma-specific algorithm.

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5. Clinical outcome data including serological response to treatment, assessment of minimal residual disease if performed locally, and survival status if known

Intervention Type
Other

Primary outcome(s)

Per-lesion sensitivity of the software to identify focal lesions, compared to a “gold standard” reading provided by a central expert radiologist. Per-lesion sensitivity of the software is defined as the proportion of lesions identified as active focal lesions by the software amongst the total of true focal lesions as defined by the central expert radiologist. This will be reported for each cohort

Key secondary outcome(s)
1. Per-lesion positive predictive value (precision) of the software to identify focal lesions, compared to a “gold standard” (ground truth) reading provided by a central expert radiologist. Per lesion positive predictive value of the software is defined as the proportion of true focal lesions, as determined by the central expert radiologist, amongst all lesions identified as active focal lesions by the software. This will be reported for each cohort
2. Overall disease burden as measured by the total diffuse disease volume (TDV) and apparent diffuse coefficient (ADC) metrics. Overall disease burden will be measured by the total diffuse disease volume (TDV) and apparent diffuse coefficient (ADC) metrics. Quantitative analysis of the diffusion-weighted MRI parameters will be performed for each cohort. Existing software will calculate ADCs using an iterative weighted linear least-square approach. Code for the fitting algorithm will be integrated as a plugin into the OsiriX radiological viewing platform. The region of interest (ROI) will be segmented semi-automatically using highest b-value (b750s/mm2) with reference to T2- weighted images. The ROI will be then transferred to the corresponding ADC map at each timepoint, and first-order histogram measures will be derived from the enclosed ADC voxel values, including mean, median, variance, skewness, kurtosis, and selected percentiles (dwMRI parameters). This will be reported for each cohort
3. Degree of perceived overall helpfulness as measured on a 4-point Likert scale (1=not helpful at all, 4=extremely helpful) (Clinical Usability Sub-Study)

Completion date
30/11/2026

Eligibility

Key inclusion criteria
Patients with a confirmed diagnosis of multiple myeloma who underwent a whole-body MRI scan as standard of care during their diagnostic (Training/Internal Validation & External Validation Cohorts) and/or treatment (Training/Internal Validation Cohort only) pathway, within the preceding 8 years, fulfilling all of the following:
1. WBMRI scan acquisition protocol included axial-diffusion-weighted MRI with at least 2 b-values
2. WBMRI scan acquisition protocol included axial Dixon T1-weighted MRI
3. WBMRI scan showed at least two radiographically active focal lesions defined as high signal on diffusion-weighted imaging, low ADC values (500-10000s/mm²) and low relative fact fraction (< 20%)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
0

Key exclusion criteria
Inadequate whole-body MRI image quality

Date of first enrolment
01/10/2024

Date of final enrolment
31/10/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Royal Marsden NHS Foundation Trust
Fulham Road
London
England
SW3 6JJ

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
England
DE22 3NE

Study participating centre
Glan Clwd Hospital
Ysbyty Glan Clwydd
Bodelwyddan
Rhyl
Wales
LL18 5UJ

Study participating centre
Basingstoke and North Hampshire Hospital
Aldermaston Road
Basingstoke
England
RG24 9NA

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 publication of the principal analysis of the primary endpoint.

IPD sharing plan summary

Available on request