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Is a PET/MRI scan better than a PET/CT scan at visualising bone lesions and their change with treatment in adults with myeloma?

Submission date
27/01/2020

Recruitment status
Recruiting

Registration date
12/02/2020

Overall study status
Ongoing

Last Edited
28/02/2025

Condition category
Cancer

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

Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-comparing-pet-mri-scan-to-pet-ct-scan-for-spotting-bone-damage-caused-by-myeloma-revamp

Background and study aims
Myeloma, a form of blood cancer, is a debilitating disease affecting 4,800 patients per year in the UK. Patients suffer from bone pain because the cancer causes bone to be destroyed. Scans and X-rays are used to create images of the bone so that the holes can be detected and measured. This is important in deciding which treatments to use and assessing how well the treatment is working. A new type of scanning method called PET/MRI might be able to show where the myeloma is most active, before there is bone destruction. This study will compare PET /MRI with another scanning method, PET/CT, in patients with myeloma who are going to be treated with a bone marrow transplant.

Who can participate?
Adults who have been newly diagnosed with myeloma

What does the study involve?
Participants will be assessed and treated as usual, except that they will have a PET/MRI scan as well as each standard PET/CT scan, so that the two scanning methods can be compared. The scans will be done before the start of treatment and after the chemotherapy that participants have before the bone marrow transplant.

What are the possible benefits and risks of participating?
Risks:
1. Participants will be required to fast for up to 6 hours prior to each PET scan. The researchers will assess the fasting for safety and will take measures, for example adjusting diabetes medication, to reduce the risks.
2. Participants will be required to lie still for up to 1 hour during the scans. They will be warned that they may experience some discomfort particularly if they have bone disease, and of course can discontinue the test if it is too uncomfortable.

3. There is a small risk of side effects from the contrast agent that is injected into the participant's vein before the scan to make structures inside their body more visible on the image. Participants will fill in a questionnaire before the procedure to enable the researchers to assess whether they might have higher risk of reactions and take appropriate actions to reduce this risk.
4. The PET/CT scan involves being exposed to radiation, which carries a small risk of side effects. This will be explained to the participants, along with measures to reduce risk.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
October 2016 to October 2026

Who is funding the study?
The National Institute for Health Research (NIHR) (UK) and the Royal College of Radiologists (UK)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
199518

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 32545, IRAS 199518

Study information

Scientific Title
Response evaluation in myeloma patients using integrated 18F-Fluorodeoxyglucose (18F-FDG) positron emission tomography/magnetic resonance imaging (PET/MRI)

Acronym
REVAMP

Study objectives

Myeloma, a form of blood cancer, is a debilitating disease affecting 4,800 patients per year [CRUK 2014]. Patients suffer from bone pain due to destructive bone lesions. Imaging plays an important role via lesion detection, therapy triage and response assessment. Skeletal survey, involving x-rays of the entire skeleton [Dimopoulos, Blood, 2011] has been the 'gold standard' but recent studies have shown it only has a sensitivity of 30% for lesion detection [Regelink et al, 2013].
Magnetic resonance imaging (MRI) may improve on this (80% versus 30% sensitivity, [Regelink, 2013]). Whole body MRI, where the skeleton can be imaged from skull base to knees, is now possible and recommended in the 2015 International Myeloma Working Group (IMWG) guidelines for baseline staging in myeloma [Dimopoulos, 2015]. For treatment response assessment a study has suggested that FDG PET/CT may better than MRI alone for assessment of response/non-response [Spinnato, 2012]].
Position Emission Tomography/MR (PET/MRI) is a new scanner that combines MRI and PET imaging. PET may highlight myeloma as areas of increased glucose metabolism, whilst the MR component provides an anatomic map.
We hypothesize that PET/MRI will improve staging and treatment response assessment. We wish to evaluate newly diagnosed myeloma patients planned for bone marrow transplantation, and compare this to PET/CT. We will develop software to quantify tumour volume pre- and post-induction chemotherapy and to assess changes in tumour function/composition e.g. metabolism, cellularity and fat content, as we hypothesize that these may change with treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/10/2016, South Central - Hampshire A Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol BS1 2NT; +44 (0)117 342 1328; nrescommittee.southcentral-hampshirea@nhs.net), ref: 16/SC/0428

Study design
Non-randomized; Interventional; Design type: Diagnosis, Imaging

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Myeloma

Interventions
Participants will be identified, screened and approached. Participants will be consented by the clinical team, research team or appropriately trained delegates. PET/CT and PET/MR appointments will be booked (pre- and post-induction chemotherapy) and safety questionnaires completed. Standard clinical pre-treatment assessments will also take place. Participants will undergo a baseline standard-of-care PET/CT and additional research PET/MRI prior to treatment commencing. They will then undergo a standard-of-care post-treatment PET/CT and additional research PET/MRI within 4-6 weeks following completion of induction chemotherapy. Patients will have further treatment (which may include bone marrow transplant) and follow-up assessment as determined by the direct clinical care team.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Myeloma bone disease detection, calculated using using focal lesion number, MRI bone marrow pattern and functional parameters including SUVmax, ADC and fat fraction parameters, assessed by PET/CT and PET/MRI at baseline and at 4-6 weeks following completion of induction chemotherapy
2. Treatment response calculated using using focal lesion number, MRI bone marrow pattern and functional parameters including SUVmax, ADC and fat fraction parameters, assessed by PET/CT and PET/MRI at baseline and at 4-6 weeks following completion of induction chemotherapy
3. Response/non-response to treatment assessed using clinical biomarkers and clinical review following completion of induction chemotherapy and following bone marrow transplant, including 100-day post-transplant bone marrow biopsy, where performed. Patients will be followed up by the clinical haematology team as per standard clinical practice.

Secondary outcome measures
-

Overall study start date
01/10/2016

Completion date
01/10/2026

Eligibility

Key inclusion criteria
Newly diagnosed with myeloma

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 20; UK Sample Size: 20

Key exclusion criteria
1. Contraindication to PET/CT or PET/MR
2. Unable to provide informed consent.

Date of first enrolment
04/01/2017

Date of final enrolment
01/10/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's Hospital
Guy's and St Thomas' NHS Foundation Trust
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Sponsor information

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Sponsor type
University/education

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http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Other

Funder Name
Royal College of Radiologists

Alternative Name(s)
The Royal College of Radiologists, RCR

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
National Institute for Health 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

Publication and dissemination plan
At the end of the study, the results will be presented at meetings and published in a high-impact peer-reviewed journal. All information will be anonymous and at no time will it be possible for patients to be identified individually.

Intention to publish date
01/10/2027

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.6	01/04/2022	13/07/2022	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 1.7	23/05/2023	17/10/2023	No	No