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A trial using a new type of scan to detect myeloma

Submission date 28/09/2023	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 08/02/2024	**Overall study status** Ongoing	
Last Edited 03/11/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
This study is investigating whether a new type of imaging scan can be used to assess patients with multiple myeloma, which is a cancer that mainly involves the bones. The scan involves injecting patients with a small dose of a radioactive antibody (radiotracer) 89Zr-belantamab. The radiotracer is made from a drug that is used to treat myeloma. It is expected to selectively accumulate in the cancer and measured using a PET scanner.

Who can participate?
Patients who have myeloma detectable by other types of imaging scan.

What does the study involve?
Up to 19 patients will be injected with the radiotracer twice and scanned up to 12 times over the course of 14-21 days to help determine to which degree and how quickly the radiotracer accumulates in the myeloma tumours. This is useful as, whilst not therapeutic, it will help understand the best time for imaging patients and also give an indication of how much radiation the patients are exposed to by the test.

What are the possible benefits and risks of participating?
Participants will be monitored closely throughout the trial and will be asked to attend regular appointments. Some visits will involve taking extra blood samples and additional radiation exposure to their normal treatment. The potential side effects of the treatments used in this trial are explained within the participant information sheet. Strict monitoring and supportive care will be given to minimise the side effects.

Cannula insertion poses known risks and only appropriately trained medical staff will carry out such procedures. Patient’s skin will be prepped with an anti-septic wipe, which very rarely can cause a skin reaction. If a patient knows they are allergic to the anti-septic prep, another sterile agent will be used. They will then feel a sharp scratch as the needle is inserted. It is exceedingly rare for complications to occur; however, multiple attempts at cannula insertion, bruising, bleeding and infection are potential risks that will be minimised as much as possible by monitoring for bleeding and using sterile equipment and the sterile non-touch technique.

All procedures will be carried out by appropriately trained healthcare professionals. Any clinically significant incidental findings during the scans will be reported to the CI and the CI will then report these to the participant via the GP and/or the appropriate clinician in Haematology.

Subjects will be exposed to an additional dose of ionising radiation as a consequence of their participation in this study. The doses chosen aim to deliver a minimal radiation exposure, compatible with a good quality PET and CT signal. In oncology 89Zr-labelled mAb studies, a minimum administration of 37 MBq is regarded as adequate for good image quality. The total radiation participants will receive over the course of this study is equivalent to approximately 28 times the average yearly exposure (2.7 mSv) from natural background radiation in the United Kingdom. The additional risk of developing a fatal malignancy as a result of these exposures has been estimated as approximately 1 in 398 for a 65-year old adult in normal health. The reduced life expectancy of the patient population to be studied will result in a lower risk for these individuals.

The number of study visits could be burdensome on participants so we have designed the study in such a way that they can decide how many scans they receive with only two or six required (depending on which part of the study they are participating in) and a maximum of 12 if they feel they are able. The study team will also schedule any safety assessments so that they can be fulfilled in as few hospital visits as possible.

Where is the study run from?
Oxford University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
September 2023 to December 2027

Who is funding the study?
GlaxoSmithKline (UK)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
1007735

Protocol serial number
PID15911

Study information

Scientific Title
89Zr-belantamab PET-CT imaging to detect myeloma

Acronym
MAGNETO

Study objectives
The main objectives of MAGNETO are to see if a new type of radioactive tracer is able to detect Myeloma during a normal PET scan. We will give participants different doses of a monoclonal antibody called Belantamab before, or at the same time of the radioactive tracer, to see if that affects how well it shows Myeloma on the scan.
1. Understand the best order and timing for scanning.
2. Understand how belantamab is absorbed, distributed and metabolized from the body.
3. Analyse the change in the amount of sBCMA over a period of time. This is important because belantamab attaches to sBCMA.
4. Measure the amount of radiation absorbed by the participant from the radioactive tracer.
5. Try and correlate uptake of the new radiotracer into Myeloma with other biomarkers in tissue and blood.
6. Compare the new radiotracer with an old one called FDG.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/02/2024, North West - Haydock Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8131; haydock.rec@hra.nhs.uk), ref: 23/NW/0315

Primary study design
Interventional

Study design
Interventional randomized

Study type(s)
Efficacy, Safety

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

Interventions

This is a single arm, multi-part study. Part 1A patients will be injected intravenously with 37MBq (±10%) of 5mg 89Zr-Belantamab at their first IMP visit (Day 0) and 40mg (5mg labelled, 35mg unlabelled) at their second IMP visit (Day 14-21) over 30-60 minutes. Part 1B patients will be injected intravenously with 40mg (5mg labelled, 35mg unlabelled) Belantamab at their first IMP visit (Day 0) over 30-60 minutes. During their second IMP visit (Day 14-21) they will be pre-dosed with 35mg of Belantamab 1 hour prior to an injection of 5mg 89Zr-Belantamab. Part 2 patients will be injected intravenously with 37MBq (±10%) of 89Zr-Belantamab at their first IMP visit (Day 0) with the dosage to be determined following analysis of results from Part 1. During their second IMP visit (Day 14-21) they will receive 89Zr-Belantamab intravenously along with variable dose of Belantamab (undisclosed for IP protection). Each injection throughout the study with be followed by up to 6 low dose PET scans. Patients will undergo a safety visit that includes an ocular examination and blood test for analysis whilst also completing a 70 day follow up visit.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Zr-belantamab [89Zr-GSK2857914], belantamab [GSK2857914]

Primary outcome(s)
Quantitative values of 89Zr-belantamab concentration and kinetics within organs in individual patients, measured using SUV values and tumour to background ratios at 6 scan time points within 6 days.

Key secondary outcome(s)
1. Visual perception and quantitative values of 89Zr-belantamab in myeloma lesions measured by Tumour: Background ratios and absolute SUV values at 3 scan time points within 6 days.
2. Degree of improvement of lesion detection and quantitation of lesion uptake after changes in Belantamab dose and schedule measured by relative change in uptake values (absolute SUV and T:B ratio) at 6 scan time points within 6 days.
3. Definition of suitable scanning sequence and time points measured by those that yield the greatest uptake in myelomatous lesions as assessed by T:B ratio and absolute SUV at 3 scan time points within 6 days.
4. Assessment of lesion detection with FDG and 89Zr-belantamab by comparison of absolute SUV values and T:B ratio using up to three time points compared to FDG PET (if available).
5. To evaluate the PK profile of Belantamab using PK parameters at up to 12 time points as participant data permits.
6. To evaluate the concentration time profile of sBCMA using summary statistics at up to 12 time points as participant data permits
7. Correlation of 89Zr-belantamab lesion uptake with biopsy and serum markers of disease using correlation graphs and statistical analyses at up to three time points
8. Evaluated organ and whole-body radiation exposure using up to 6 scan time points within 6 days

Completion date
31/12/2027

Eligibility

Key inclusion criteria

1. Any individual with a confirmed case of multiple myeloma or multifocal plasmacytoma with lesions demonstrable on imaging performed within 4 weeks of start of trial.
2. At least one skeletal myeloma deposit >0.5 cm in diameter.
3. Patients who are able to tolerate the study protocol.
4. Participant is willing and able to give informed consent for participation in the trial.
5. Participants must be aged 30 years or above.
6. In the Investigator's opinion, is able and willing to comply with all trial requirements.
7. Willing to allow his or her General Practitioner and consultant, if appropriate, to be notified of participation in the trial.
8. Participants with a history of autologous SCT are eligible for study participation provided the following eligibility criteria are met:
8.1. ASCT was >100 days prior to initiating study treatment, and
8.2. No active bacterial, viral, or fungal infection(s) present.
9. All prior treatment-related toxicities (defined by National Cancer Institute Common Toxicity Criteria for Adverse Events [NCI-CTCAE] v5.0) must be ≤ Grade 1 at the time of enrollment, except for alopecia.
10. Participant has clinically acceptable laboratory results within 4 weeks of enrolment
11. A female participant is eligible to participate if she is of non-childbearing potential, defined as one of the following:
11.1. ≥ 45 years of age and has not had menses for > 2 years
11.2. Patients who have been amenorrhoeic for < 2 years without history of a hysterectomy and oophorectomy must have a follicle stimulating hormone value in the postmenopausal range upon screening evaluation.
11.3. A high follicle stimulating hormone (FSH) level in the postmenopausal range may be used to confirm a postmenopausal state in women not using hormonal contraception or hormonal replacement therapy (HRT). However, in the absence of 24 months of amenorrhea, confirmation with more than one FSH measurement is required. In questionable cases a blood sample with simultaneous FSH >40 MIU/mL and estradiol.
11.4. Females on HRT and whose menopausal status is in doubt will be required to use one of the non-estrogen hormonal highly effective contraception methods if they wish to continue their HRT during the study. Otherwise, they must discontinue HRT to allow confirmation of postmenopausal status before study enrolment.
11.5. Post-hysterectomy, post-bilateral oophorectomy, or post-tubal ligation. Documented hysterectomy or oophorectomy must be confirmed with medical records of the actual procedure or confirmed by an ultrasound. Tubal ligation must be confirmed with medical records of the actual procedure.
12. Male participants are eligible to participate if they agree to the following from the time of first dose of study until 6 months after the last dose of belantamab to allow for clearance of any altered sperm:
12.1. Refrain from donating sperm
PLUS either:
12.2. Be abstinent from heterosexual intercourse as their preferred and usual lifestyle (abstinent on a long term and persistent basis) and agree to remain abstinent.
OR
12.3. Must agree to use contraception/barrier:
12.3.1. Agree to use a male condom, even if they have undergone a successful vasectomy, and female partner to use an additional highly effective contraceptive method with a failure rate of <1% per year as described in section 11.2 when having sexual intercourse with a woman of

childbearing potential (including pregnant females).
12.3.2. Contraceptive use should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
30 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. The presence of only extramedullary lesions as determined by imaging performed within 4 weeks of start of trial.
2. Significant renal (infection, requirement for dialysis or any other condition that could affect participant's safety) or hepatic (current unstable liver or biliary disease defined by the presence of ascites, encephalopathy, coagulopathy, hypoalbuminemia, esophageal or gastric varices, persistent jaundice, or cirrhosis. Note: Stable non-cirrhotic chronic liver disease (including Gilbert' s syndrome or asymptomatic gallstones) or hepatobiliary involvement of malignancy is acceptable if otherwise meets entry criteria) impairment.
3. Participants with isolated proteinuria resulting from MM are eligible, provided they fulfil inclusion criteria
4. Participant with life expectancy of less than 6 months.
5. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial.
6. Participants who have participated in another research trial involving an unlicensed product in the past 12 weeks.
7. Participants that have undertaken more than two rounds of chemotherapy.
8. Patients who would not be able to tolerate lying supine, within the gantry of a PET-CT scanner, with a total duration of up to 1 hour.
9. The investigator is responsible for review of medical history, menstrual history, and recent sexual activity to decrease the risk for inclusion of a woman with a nearly undetected pregnancy.
10. Participant currently has corneal epithelial disease, except nonconfluent superficial punctate keratitis (SPK).
11. Patients with ongoing or recent BCMA targeted myeloma treatment which can be expected to affect lesion BCMA expression.

12. Participant must not have used an investigational anti-myeloma drug within 14 days or five half-lives, whichever is shorter, preceding the first dose of study drug.
13. Participant must not have evidence of cardiovascular risk including any of the following:
13.1. Evidence of current clinically significant uncontrolled arrhythmias, including clinically significant ECG abnormalities such as 2nd degree (Mobitz Type II) or 3rd degree atrioventricular (AV) block.
13.2. History of myocardial infarction, acute coronary syndromes (including unstable angina), coronary angioplasty, or stenting or bypass grafting within three (3) months of Screening.
13.3. QTcF interval >450 msec (QT interval corrected for heart rate according to Fridericia's formula), and/or hypokalemia, and/or family history of long QT syndrome.
13.4. Class III or IV heart failure as defined by the New York Heart Association functional classification system, [NYHA, 1994]
13.5. Uncontrolled hypertension
14. Known immediate or delayed hypersensitivity reaction or idiosyncrasy to drugs chemically related to belantamab or any of the components of the study treatment. History of severe hypersensitivity to other mAbs.
15. Smouldering MM, Symptomatic amyloidosis, active POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal plasma proliferative disorder, skin changes) or active plasma cell leukaemia at the time of screening.
16. Any serious and/or unstable pre-existing medical, psychiatric disorder or other conditions (including lab abnormalities) that could interfere with participant's safety, obtaining informed consent or compliance to the study procedures.
17. Participant must not have received a live or live-attenuated vaccine within 30 days prior to first dose of belantamab.
18. Patients may not be enrolled on BCMA therapeutic clinical trials for treatment whilst on this study.
19. Ongoing Grade 2 or higher peripheral neuropathy or neuropathic pain.
20. Prior allogenic stem cell transplant. NOTE – Participants who have undergone syngeneic transplant will be allowed, only if no history of GvHD.
21. Any major surgery within 4 weeks prior to the first dose of study drug. Exception allowed for bone stabilizing surgery after consultation with PI.
22. Evidence of active mucosal or internal bleeding.
23. Active infection requiring treatment.
24. Known HIV infection
25. Presence of hepatitis B surface antigen (HbsAg), or hepatitis B core antibody (HbcAb), at screening or within 3 months prior to first dose of study treatment. Note: presence of Hep B surface antibody (HBsAb) indicating previous vaccination will not exclude a participant.
26. Positive hepatitis C antibody test result or positive hepatitis C RNA test result at screening or within 3 months prior to first dose of study treatment.

Date of first enrolment
15/05/2025

Date of final enrolment
30/07/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Churchill Hospital
Churchill Hospital
Old Road
Headington
Oxford
England
OX3 7LE

Sponsor information

Organisation
Oxford University Hospitals NHS Trust

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes