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Blood cancer clinical trials long-term follow-up using integrated Healthcare Systems Data

Submission date
17/09/2026

Recruitment status
Recruiting

Registration date
01/10/2026

Overall study status
Ongoing

Last Edited
01/10/2026

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Clinical trials play an important role in finding better treatments for blood cancers. However, many trials rely on regular hospital visits and special trial paperwork to follow patients over many years. This can be tiring for patients, takes a lot of time for doctors and nurses, and can be expensive to manage. This is especially true for conditions like multiple myeloma, where people may live for many years after joining a trial. At the same time, the NHS already routinely collects information about hospital visits and deaths as part of everyday care (this is called healthcare systems data), but we do not yet know how well this information works in blood cancer trials. The BLISS study will link data we already hold at the Clinical Trials Research Unit (CTRU) in Leeds with healthcare systems data from NHS England. We're only looking at the data from 10 clinical trials which were run at the CTRU and all of these trials have now closed. We will use the information we receive from NHS England to answer information research questions, such as:
1. Whether treatments have had a long-term benefit
2. How frailty is assessed
3. How bone disease is treated
4. If trials represent all patients who get blood cancers

Who can participate?
The study involves participants who consented to take place in one or more of the completed clinical trials which were run at the Leeds CTRU between 2008 and 2021: Myeloma X, MUKOne, MUKFour, MUKSix, MUKEight, Myeloma XI, MUKThree, MUK Five, MUKSeven, or MUKTwelve. At the time these trials took place, we did not ask for consent for linkage to data records held by national providers (such as a NHS England). As these trials have now closed and some people may have moved away, it is not possible to contact everyone. We have therefore obtained permission to obtain follow up data from the Health Research Authority (who take advice from the Confidentiality Advisory Group). This involves sharing a limited amount of personal data (NHS Number, date of birth and sex) with NHS England to obtain linked healthcare systems data. If you took part in one of these trials and are happy to be included in the study, you do not need to do anything. If you took part in one of these trials and do not wish to be included in the study, you can opt out by visiting https://ctru.leeds.ac.uk/bliss/ or contacting a member of the BLISS team.
Any person who took part in one of these trials and withdrew their consent from further data

collection will not be included in the BLISS study. After the data linkage has occurred, a persons data is de identified and researchers will not be able to see identifiable data.

What does the study involve?
In this study, we are bringing together information from several UK multiple myeloma clinical trials with existing NHS records, such as national death registrations, cancer records, and hospital admissions. We will carefully compare the information collected during the trials with NHS records to see how accurate and complete the routine data are. In particular, we want to understand whether NHS death records can be reliably used to track long term survival, instead of relying solely on trial follow up visits.

What are the possible benefits and risks of participating?
This research could help to answer important research questions about myeloma more quickly. It could do this by making it easier to follow people for longer periods and improve our understanding of long-term outcomes in blood cancer. It can also help to make future trials simpler and less demanding for patients by reducing the need for extra hospital appointments and paperwork. Overall, this approach could help make clinical research more efficient, more patientfriendly, and still produce high quality information to improve care.

Where is the study run from?
University of Leeds (UK)

When is the study starting and how long is it expected to run for?
February 2026 to April 2030

Who is funding the study?
Blood Cancer UK (BCUK)

Who is the main contact?
Lesley Smith/Sharon Gillson, Ctru-bliss@leeds.ac.uk

Plain English summary under review with external organisation

Contact information

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Additional identifiers

Integrated Research Application System (IRAS)
343775

Study information

Scientific Title
A data linkage study integrating randomised clinical trials with national Healthcare Systems Data

Acronym
BLISS

Study objectives
The BLISS platform will be established as a research database, including blood cancer clinical trials linked to Healthcare Systems Data (HSD). The initial research priorities cover the following aims:
1. To use routinely collected mortality data to assess long-term overall survival in a series of myeloma clinical trials
2. To conduct a series of data utility comparison studies to assess the quality and reliability of HSD in comparison to trial-specific collected data relating to mortality, treatment during and after trial, second cancer incidence, and adverse events including infection, fracture, venous thromboembolism and cardiovascular disease
3. To assess diversity and representativeness in trial participants and outcomes
4. To derive time to next treatment from HSD and evaluate if it can be used as a surrogate endpoint for progression free survival in myeloma clinical trials
5. To assess and compare methods of defining frailty based on HSD and asses the clinical outcomes and prognostic ability of these indices
6. To identify and describe bone-related treatment and outcomes

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/07/2025, East of England - Cambridge Central Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207 104 8241; cambridgecentral.rec@hra.nhs.uk), ref: 25/EE/0099

Primary study design
Observational

Secondary study design
Data linkage study

Study type(s)

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

Interventions
This data linkage study includes participants from multiple myeloma Randomised Controlled Trials (RCTs) conducted by the University of Leeds between 2008 and 2021. NHS England will link these participants to HSD, including deaths and cancer registrations, systemic anticancer therapy, radiotherapy, and Hospital Episode Statistics.

We will compare trial-collected outcomes with those derived from HSD, including mortality, treatment, second cancer incidence and major adverse events. Long-term overall survival will be estimated using national mortality data. HSD-derived demographic and clinical variables will be used to assess population representativeness relative to the wider myeloma population. Time to next treatment will be derived and evaluated as a surrogate for progression free survival. HSD-derived frailty measures will be examined for prognostic utility, and radiotherapy and hospital records will be analysed to characterise bone related treatments and skeletal complications.

Intervention Type
Other

Primary outcome(s)
1. Long-term overall survival measured using time from randomisation to death from any cause or last follow-up at 15-years follow-up

2. Population representativeness measured using national data to compare trial participant characteristics at baseline

3. Time to next treatment measured using routinely collected treatment data compared to trial-specific data at different lines of treatment

Key secondary outcome(s)

Completion date
30/04/2030

Eligibility

Key inclusion criteria
1. Participants must have taken part in at least one of the completed multiple myeloma clinical trials conducted by the University of Leeds CTRU between 2008 and 2021 as per below:
1.1. MUKOne: ISRCTN90889843
1.2. MUKThree: ISRCTN24989786
1.3. MUKFour: ISRCTN08577602
1.4. MUKFive: ISRCTN17354232
1.5. MUKSix: ISRCTN59395590
1.6. MUKSeven: ISRCTN24593488
1.7. MUKEight: ISRCTN58227268
1.8. MUKTwelve: ISRCTN15028850
1.9. Myeloma X: ISRCTN60123120
1.10. Myeloma XI: ISRCTN49407852
2. Participants must have been recruited to one or more of the listed clinical trials at a trial location based in England

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Participants who have withdrawn from further data collection from any of the listed multiple myeloma clinical trials
2. Participants recruited to a trial location (involved in one more of the listed clinical trials) outside of England
3. Participants who have opted out of the data linkage study

Date of first enrolment
13/02/2026

Date of final enrolment
31/05/2028

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Wales

Study participating centre
University of Leeds
Woodhouse Lane
Leeds
England
LS2 9JT

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type

Funder Name
Blood Cancer UK

Alternative Name(s)
Blood Cancer UK Research

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		11/05/2026	17/09/2026	Yes	No
Participant information sheet	version 1.0		17/09/2026	No	Yes
Poster results	version 3.0		17/09/2026	No	No
Study website			17/09/2026	No	No