Frailty-adjusted therapy in transplant noneligible patients with newly diagnosed multiple myeloma

Submission date	Recruitment status No longer recruiting	Prospectively registered	
277172020		[X] Protocol	
Registration date 18/01/2021	Overall study status Ongoing	Results	
Last Edited 04/03/2024	Condition category Cancer	Individual participant data	
		[] Record updated in last year	

Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-of-ixazomiblenalidomide-and-dexamethasone-for-people-with-myeloma-fitness

Background and study aims

Myeloma is is a type of bone marrow cancer diagnosed in around 5500 patients in the UK each year. The development of treatments has increased life expectancy in all patients, but these have been less effective in older and frailer patients. There is no evidence to suggest their myeloma is more aggressive, so it needs to be asked why this is the case. Research is beginning to look at older myeloma patients who are ineligible for transplants. Myeloma XI, a previous trial where 1840 of these patients were recruited, has shown that treatment outcomes were not necessarily associated with different combinations of treatment. The aim of this study is to compare standard and frailty-adjusted induction treatment with ixazomib, lenalidomide and dexamethasone and maintenance lenalidomide to lenalidomide plus ixazomib.

Who can participate?

Newly diagnosed myeloma patients, above the age of 18, who are not eligible for a stem cell transplant

What does the study involve?

All participants receive induction treatment with ixazomib, lenalidomide and dexamethasone and are randomly allocated to either frailty score-adjusted treatment or standard upfront treatment followed by toxicity-dependent dose modifications during treatment. Following 12 cycles of induction treatment participants alive and progression-free undergo a second randomisation. In the second phase of the trial, patients will be tested to assess whether lenalidomide and ixazomib are effective as a maintenance treatment. Patients will either receive lenalidomide and ixazomib, or lenalidomide and placebo (something that has a similar taste and appearance to ixazomib but has no effect on the person) to test this.

What are the possible benefits and risks of participating?

Evidence from previous trials has shown that patients who are older and living with other health

issues do not stay on standard treatment for as long as younger, fitter patients. This study will explore whether tailoring the medication will increase the durability of treatment in older patients to ensure a longer benefit and therefore reduce the risk of having to stop treatment early due to side effects. Participants will be helping to answer important questions and it is hoped that this will improve treatment now and for future patients.

At the moment, neither the IRD induction treatment nor maintenance therapy with either lenalidomide alone or in combination with ixazomib is available on the NHS for the treatment of newly diagnosed myeloma, and so this study gives access to these treatments. Previous studies have shown that maintenance therapy with lenalidomide can increase the length of disease remission. The goal of this study is to gain a greater understanding of the various treatment options available for myeloma patients, how they compare to each other and how they are best delivered to patients. This may or may not be a better approach to treating myeloma compared to what doctors do currently.

There are potential risks associated with the study as well as potential side effects from the trial treatments and drugs. A small number of patients may develop additional types of cancer, and it is possible that this risk may be increased with lenalidomide treatment. Some medications, and complementary health supplements such as St John's Wort, should not be used during this study as they may interact with the study medications.

Patients who take part in this study are potentially at risk of becoming sterile or infertile. This is also the case with other chemotherapy treatments participants would likely receive if they were not on the study. If appropriate, counselling and a referral for fertility assessment and preservation will be available. Some patients with myeloma find that they can continue to work during treatment.

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

When is the study starting and how long is it expected to run for? August 2017 to August 2027

Who is funding the study?

The study is largely funded by Cancer Research UK. Some of the costs of the drugs being used in the study, as well as some additional funding for the running of the study, is being provided by the companies who make two of the drugs being investigated, Takeda (ixazomib) and Celgene (lenalidomide).

Who is the main contact? Rowena Henderson ctru_myelomaxiv@leeds.ac.uk

Contact information

Type(s) Scientific

Contact name Ms Rowena Henderson

Contact details Leeds Institute of Clinical Trials Research Clinical Trials Research Unit University of Leeds Leeds United Kingdom LS2 9JT +44 (0)113 343 1159 ctru_myelomaxiv@leeds.ac.uk

Type(s)

Public

Contact name Ms Sharon Gillson

Contact details Leeds Institute of Clinical Trials Research Clinical Trials Research Unit University of Leeds Leeds United Kingdom LS2 9JT +44 (0)113 34 39368 ctru_myelomaxiv@leeds.ac.uk

Additional identifiers

EudraCT/CTIS number 2018-003590-10

IRAS number 234453

ClinicalTrials.gov number NCT03720041

Secondary identifying numbers Version 2.0, 10th October 2019, IRAS 234453

Study information

Scientific Title

A phase III trial to compare standard and frailty-adjusted induction therapy with ixazomib, lenalidomide and dexamethasone (IRD) and maintenance lenalidomide (R) to lenalidomide plus ixazomib (IR)

Acronym FiTNEss (UK-MRA Myeloma XIV)

Study objectives

At R1: That there is a difference in the proportion of patients, categorised as "unfit" or "frail" at trial entry, requiring early cessation of treatment (within 60 days of randomisation) between standard up-front (reactive) or frailty score-adjusted (adaptive) dose modifications, with superiority of the frailty score-adjusted (adaptive) dose modifications anticipated. The null hypothesis is that there is no difference.

At R2:

That there is a difference in progression-free survival between lenalidomide + placebo (R) and lenalidomide + ixazomib (R + I) maintenance therapy with superiority of R + I maintenance therapy anticipated. The null hypothesis is that there is no difference.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 11/09/2019, North East – Tyne & Wear South Research Ethics Committee (NHSBT Newcastle Blood & Transplant Centre Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44(0) 207 1048084; nrescommittee.northeast-tyneandwearsouth@nhs.net), REC ref: 19/NE/0215

Study design

Multicenter interventional placebo-controlled double-blind randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s) Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Multiple myeloma

Interventions

All participants receive 12 cycles of induction treatment with ixazomib, lenalidomide and dexamethasone and are randomised on a 1:1 basis at trial entry to the use of frailty scoreadjusted up-front dose reductions vs. standard up-front dosing followed by toxicity dependent reactive dose modifications during therapy.

Randomisation 1 will be completed using a computer generated minimisation algorithm that incorporates a random element to ensure that all arms are well balanced for specific participant characteristics, details of which will be required at randomisation.

Participants randomised to the frailty adjusted arm will undergo assessment for frailty according to the IMWG Frailty Index be categorised as fit, unfit or frail.

Following 12 cycles of induction treatment participants alive and progression-free undergo a second randomisation on a 1:1 basis to maintenance treatment with lenalidomide plus placebo versus lenalidomide plus ixazomib. Participants and their treating physicians will be blinded to maintenance allocation.

Randomisation 2 will be completed using a computer generated minimisation algorithm that incorporates a random element to ensure that all arms are well balanced for specific participant characteristics, details of which will be required at randomisation.

Ixazomib is an oral hard gelatin capsule that is taken orally. Lenalidomide is a hard capsule that is taken orally. Dexamethasone is a hard capsule that is taken orally. The placebo is an oral hard gelatin capsule that is taken orally.

All participants will receive 12 cycles of induction treatment, each treatment cycle is 28 days in length.

Participants who are randomised to the standard up-front dosing followed by toxicity dependent dose-modifications (reactive) arm will receive: 4 mg of ixazomib on days 1, 8 and 15 25 mg of lenalidomide on days 1-21 40 mg of dexamethasone in participants ≤75 years or 20 mg dexamethasone in participants >75 years on days 1, 8, 15, 22

Participants randomised to the frailty score-adjusted dosing arm (adaptive) and are categorised as FIT will receive:

4 mg of ixazomib on days 1, 8 and 15 25 mg of lenalidomide on days 1-21 40 mg of dexamethasone on days 1, 8, 15, 22

Participants randomised to the frailty score-adjusted dosing arm (adaptive) and are categorised as UNFIT will receive: 4 mg of ixazomib on days 1, 8 and 15 15 mg of lenalidomide on days 1-21 20 mg of dexamethasone on days 1, 8, 15, 22

Participants randomised to the frailty score-adjusted dosing arm (adaptive) and are categorised as FRAIL will receive: 4 mg of ixazomib on days 1, 8 and 15 10 mg of lenalidomide on days 1-21 10 mg of dexamethasone on days 1, 8, 15, 22

Participants who progress to maintenance and are randomised to receive lenalidomide and placebo will receive: 10 mg of lenalidomide on days 1-21 4 mg of placebo on days 1, 8, 15

Participants who progress to maintenance and are randomised to receive lenalidomide and placebo will receive:

10 mg of lenalidomide on days 1-21 4 mg of ixazomib on days 1, 8, 15

The duration of trial treatment for individual participants will vary, as treatment will continue until disease progression or intolerable toxicity. On average, it is expected that a participant will receive trial treatment for an average of 37 months: they will receive 12 cycles of IRD induction, followed by a median of 25 cycles of maintenance. All cycles last for 28 days.

Intervention Type

Drug

Phase III

Drug/device/biological/vaccine name(s)

Ixazomib, lenalidomide, dexamethasone

Primary outcome measure

Randomisation 1 (R1): Early treatment cessation (yes or no). Participants will be defined to have ceased treatment early if they die, progress, or are withdrawn from treatment (by a treating clinician) or withdraw consent for trial treatment, within 60 days of R1.

Randomisation 2 (R2): Progression-free survival (PFS-R2): time of first documented evidence of disease progression or death from any cause. Individuals who are lost to follow-up or progression-free at the time of analysis will be censored at their last known date to be alive and progression-free

Secondary outcome measures

Measured using eCRFs and patient records unless otherwise indicated:

1. Progression-free survival (PFS-R1): the time from R1 to the time of first documented evidence of disease progression or death from any cause. Disease progression is defined according to the IMWG Uniform Response Criteria for Multiple Myeloma

2. Time to progression: the time from randomisation to the date of first documented evidence of disease progression

3. Time to Progression-free survival two (PFS2): time from randomisation to the time of the second documented disease progression or death from any cause

4. Overall survival (OS): the time from randomisation to the time of death from any cause 5. Survival after progression: time from the date of first documented evidence of disease progression to the date of death from any cause

6. Death within 12 months of R1 (yes or no)

7. Overall response rate (ORR): whether a participant had sCR, CR, VGPR, PR, MR, SD or PD at the end of induction according to the IMWG Uniform Response Criteria for Multiple Myeloma 8. Attainment of ≥VGPR (yes or no)

9. Attainment of Minimal Residual Disease (MRD) negativity (yes or no, according to the IMWG MRD criteria)

10. Duration of response (DoR): time from the first observation of response ≥ PR, following R1, to the time of first documented evidence of disease progression or death confirmed related to progression

11. Time to improved response: time from the date of R2 to the date the response category is first improved based on the Modified International Uniform Response Criteria for Multiple Myeloma

12. Time to next treatment: time from R1 to the start date of the next line of treatment (i.e. treatment following documented evidence of progressive disease) or death from any cause 13. Treatment compliance and total amount of therapy delivered:

13.1. Did the participant receive 12 cycles of induction treatment (yes or no)

13.2. Number of induction and maintenance cycles which the participant received. This may be extended to consider the percentage of protocol dose delivered. For each treatment (ixazomib, lenalidomide, dexamethasone) this will be defined as the total dose received in a cycle compared to the total dose the participant should have received in the cycle without modifications, averaged across all cycles of treatment

14. Toxicity and safety reported based on the adverse events, as graded by CTCAE V5 and determined by routine clinical assessments at each centre. The number of SAEs will be reported according to MedDRA System Organ Class. All second primary malignancies will be reported based on information collected on the CRF

15. Quality of Life (QoL) using the patient-reported outcome measures; EORTC-QLQ-C30, EORTC-QLQ-MY20 and EQ-5D (3 Level) at R1, after cycles 2,6 and 12 during induction treatment. They are also collected after cycles 6 and 12 during maintenance treatment

16. Cost-effectiveness: cost per incremental QALY below £20,000 and/or a positive incremental net monetary benefit. For R1, the cost-effectiveness of standard dose IRD vs frailty adjusted dose IRD will be analysed. For R2, the cost-effectiveness of maintenance therapy using R vs R+I will be analysed

Added 07/07/2022:

17. Event-free survival (EFS) is measured from randomisation to the first instance of one of the following events; death, progression, discontinuation of the randomised treatment, a grade 4 haematological toxicity or a non-haematological toxicity ≥grade 3

Overall study start date

15/08/2017

Completion date

31/08/2027

Eligibility

Key inclusion criteria

Inclusion criteria for Randomisation 1 (R1):

1. Newly diagnosed as having MM according to the updated IMWG diagnostic criteria 2014 requiring treatment

- 2. Not eligible for stem cell transplant
- 3. Aged at least 18 years

4. Meet all of the following blood criteria within 14 days before R1:

4.1. Haematological:

4.1.1. Absolute neutrophil count (ANC) \geq 1 x 10^9/l. Unless the participant has a known /suspected diagnosis of familial or racial neutropenia in which case an ANC \geq 0.75 x 10^9/l is allowed. The use of growth factor support is permitted

4.1.2. Platelet count \geq 50 x 10^9/l, or, in the case of heavy bone marrow infiltration (\geq 50%) which in the opinion of the investigator is the cause of the thrombocytopenia and provided

appropriate supportive measures and patient monitoring are in place, platelet count \geq 30 x 10^9 /l is permitted. Please note: Platelet transfusions are not allowed \leq 3 days prior to randomisation in order to meet these values

4.1.3. Haemoglobin ≥80 g/l. The use of red blood cell transfusions is permitted

4.2. Biochemical:

4.2.1. Total bilirubin ≤ 3 x upper limit of normal (ULN)

4.2.2. Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) ≤3 x ULN

5. Meet the pregnancy prevention requirements

6. Able to provide written informed consent

Inclusion criteria for Randomisation 2 (R2):

1. Randomised into the FiTNEss (Myeloma XIV) trial and received induction chemotherapy with ixazomib and lenalidomide continued for 12 cycles

2. Achieved at least MR at the end of IRD induction according to the IMWG Uniform Response Criteria for Multiple Myeloma, with no evidence of progression prior to R2

3. Meet all of the following blood criteria within 14 days before R2:

3.1. Haematological:

3.1.1. Absolute neutrophil count (ANC) ≥1 x 10^9/l. Unless the participant has a known /suspected diagnosis of familial or racial neutropenia in which case an ANC ≥0.75 x 10^9/l is allowed. The use of growth factor support is permitted

3.1.2. Platelet count \geq 50 x 10^9/l. Please note: Platelet transfusions are not allowed \leq 3 days prior to randomisation in order to meet these values

3.1.3. Haemoglobin ≥80 g/l. The use of red blood cell transfusions is permitted

3.2. Biochemical:

3.2.1. Total bilirubin ≤3 x upper limit of normal (ULN)

3.2.2. Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) ≤3 x ULN

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants 740

Total final enrolment 733

Key exclusion criteria

Exclusion criteria at R1:

1. Smouldering MM, MGUS, solitary plasmacytoma of bone, or extramedullary plasmacytoma (without evidence of MM)

2. Received previous treatment for MM, with the exception of local radiotherapy to relieve bone pain or spinal cord compression, prior bisphosphonate treatment, or corticosteroids as long as the total dose does not exceed the equivalent of 160 mg dexamethasone

3. Known resistance, intolerance or sensitivity to any component of the planned therapies

4. Prior or concurrent invasive malignancies except the following:

4.1. Adequately treated basal cell or squamous cell skin cancer

4.2. Incidental finding of low grade (Gleason 3+3 or less) prostate cancer requiring no intervention

4.3. Adequately treated carcinoma in situ of the breast or cervix no longer requiring medical or surgical intervention

4.4. Any cancer from which the subject has been disease-free for at least 3 years 5. Pregnant, lactating or breastfeeding female participants

6. Major surgery within 14 days before randomisation. This would include surgical intervention for relief of cord compression but does not include vertebroplasty or kyphoplasty

7. Systemic treatment, within 14 days before the first dose of ixazomib with strong CYP3A inducers (e.g. rifampicin, rifabutin, carbamazepine, phenytoin, phenobarbital), or use of St John's wort

8. Any concomitant drug therapy which, in the opinion of the investigator, may lead to an unacceptable interaction with any of the agents ixazomib, lenalidomide, dexamethasone, and that cannot be safely stopped prior to trial entry. Full details of interactions can be found in the SPCs

9. Known gastrointestinal (GI) disease or GI procedure that could interfere with the oral absorption or tolerance of trial treatment, including difficulty swallowing

10. \geq Grade 2 peripheral neuropathy

11. Known HIV positive

12. Participant has current or prior hepatitis B surface antigen-positive or hepatitis C antibody positive. Participants must have screening conducted within 14 days before R1

13. Active systemic infection

14. Any other medical or psychiatric condition which, in the opinion of the investigator,

contraindicates the participant's participation in this study

15. Receipt of live vaccination within 30 days prior to R1

Exclusion criteria for R2:

1. Received any anti-myeloma therapy other than their randomised trial treatment, with the exception of local radiotherapy to relieve bone pain (in the absence of disease progression), or bisphosphonate treatment

2. SD or disease progression according to the IMWG Uniform Response Criteria for Multiple Myeloma (see Appendix 2)

3. Known resistance, intolerance or sensitivity to ixazomib or lenalidomide that required cessation of either agent during induction

4. Developed any malignancy since R1 except the following:

4.1. Adequately treated basal cell or squamous cell skin cancer

4.2. Incidental finding of low grade (Gleason 3+3 or less) prostate cancer requiring no intervention

4.3. Adequately treated carcinoma in situ of the breast or cervix no longer requiring medical or surgical intervention

5. Pregnant, lactating or breastfeeding female participants

6. Major surgery within 14 days before randomisation. This does not include vertebroplasty or kyphoplasty

7. Systemic treatment, within 14 days before the first dose of ixazomib with strong CYP3A inducers (e.g. rifampicin, rifabutin, carbamazepine, phenytoin, phenobarbital), or use of St John's wort

8. Known gastrointestinal (GI) disease or GI procedure that could interfere with the oral absorption or tolerance of trial treatment, including difficulty swallowing

9. \geq Grade 2 peripheral neuropathy, or grade 1 with pain

10. Known HIV positive

11. Current or known hepatitis B surface antigen positive or hepatitis C antibody positive

12. Active systemic infection

13. Any other medical or psychiatric condition which, in the opinion of the investigator, contraindicates the participant's continued participation in this study
14. Receipt of live vaccination within 30 days prior to R1 or receipt of live vaccination at any point during the trial prior to R2

Date of first enrolment 04/08/2020

Date of final enrolment 04/02/2024

Locations

Countries of recruitment England

Scotland

United Kingdom

Wales

Study participating centre Royal Devon & Exeter Hospital Barrack Road Devon Exeter United Kingdom EX2 5DW

Study participating centre Cheltenham Hospital Sandford Road Cheltenham United Kingdom GL53 7AN

Study participating centre James Cook University Hospital Marton Road Middlesbrough United Kingdom TS4 3BW

Study participating centre Singleton Hospital

Sketty Lane Swansea United Kingdom SA2 8QA

Study participating centre

Queen's Hospital Romford

Haematology & Oncology Department Queens Hospital Rom Valley Way Romford United Kingdom RM7 0AG

Study participating centre

Huddersfield Royal Infirmary Acre Street Lindley Huddersfield United Kingdom HD3 3EA

Study participating centre Calderdale Royal Hospital Halifax United Kingdom HX3 0PW

Study participating centre Sunderland Royal Hospital Kayll Road Sunderland United Kingdom SR4 7TP

Study participating centre South Tyneside Hospital Harton Lane South Shields United Kingdom NE34 0PL

Study participating centre Kent and Canterbury Hospital Ethelbert Road Canterbury United Kingdom CT1 3NG

Study participating centre

William Harvey Hospital Kennington Road Willesborough Ashford United Kingdom TN24 0LZ

Study participating centre Queen Elizabeth Hospital the Queen Mother St Peters Road Margate United Kingdom CT9 4AN

Study participating centre Colchester Hospital Turner Road Colchester United Kingdom CO4 5JL

Study participating centre Gloucestershire Royal Hospital Great Western Road Gloucester United Kingdom GL1 3NN **Study participating centre Kettering General Hospital** Rothwell Road Kettering United Kingdom NN16 8UZ

Study participating centre Kings College Hospital Denmark Hill London United Kingdom SE5 9RS

Study participating centre Princess Royal University Hospital Farnborough Common Orpington United Kingdom BR6 8ND

Study participating centre Blackpool Victoria Hospital Whinney Heys Road Blackpool United Kingdom FY3 8NR

Study participating centre Trafford General Hospital

Moorside Road Davyhulme Manchester United Kingdom M41 5SL

Study participating centre Manchester Royal Infirmary Oxford Road Manchester United Kingdom M13 9WL

Study participating centre Wythenshaw Hospital Southmoor Road Wythensahwe Manchester United Kingdom M23 9LT

Study participating centre Freeman Hospital High Heaton Tyne and Wear Newcastle Upon Tyne United Kingdom NE7 7DN

Study participating centre Aberdeen Royal Infirmary Foresterhill Road Aberdeen United Kingdom AB25 2ZN

Study participating centre Ninewells Hospital Dundee United Kingdom DD1 9SY

Study participating centre Norfolk & Norwich University Hospital Colney Lane Norwich United Kingdom NR4 7UY

Study participating centre

Southmead Hospital Bristol United Kingdom BS10 5NB

Study participating centre Peterborough City Hospital Edith Cavell Campus Bretton Gate Peterborough United Kingdom

PE3 9GZ

Study participating centre Hinchingbrooke Hospital Huntingdon United Kingdom PE29 6NT

Study participating centre Nottingham City Hospital Hucknall Road Nottingham United Kingdom NG5 1PB

Study participating centre Royal Berkshire Hospital London Road Reading United Kingdom RG1 5AN

Study participating centre Royal Bournemouth Hospital Castle Lane East Bournemouth United Kingdom BH7 7DW

Study participating centre Friarage Hospital Northallerton United Kingdom DL6 1JG

Study participating centre St George's Hospital Blackshaw Road London United Kingdom SW17 0QT

Study participating centre St Helens Hospital Marshalls Cross Road

St. Helens United Kingdom WA9 3DA

Study participating centre

Whiston Hospital Warrington Road Prescot United Kingdom L35 5DR

Study participating centre Torbay Hospital Lowes Bridge

Torquay United Kingdom TQ2 7AA

Study participating centre

Bristol Haematology & Oncology Centre Bristol Royal Infirmary King Edward Yard Marlborough Hill Bristol United Kingdom BS2 8HW

Study participating centre Royal Derby Hospita Uttoxeter Road Derbym United Kingdom DE22 3NE

Study participating centre University College London Hospital 235 Euston Road London United Kingdom NW1 2BU

Study participating centre Royal Albert Edward Infirmary Wigan Lane Wigan United Kingdom WN1 2NN

Study participating centre Leicester Royal Infirmary Aylestone Road Leicester United Kingdom LE2 7LG

Study participating centre Derriford Hospital Derriford Road

Crownhill Plymouth United Kingdom PL6 8DH Study participating centre Worthing Hospital

Lyndhurst Road Worthing United Kingdom BN11 2DH

Study participating centre St Richards Hospital Spitafield Lane Chichester United Kingdom PO19 6SE

Study participating centre The County Hospital Stonebow Road Hereford United Kingdom HR1 2BN

Sponsor information

Organisation University of Leeds

Sponsor details

UoL/LTHT Joint Sponsor QA Office (CTIMPs) St James' University Hospital Leeds England United Kingdom LS2 9JT +44 (0)1133432813 ctru_myelomaxiv@leeds.ac.uk

Sponsor type University/education

Website http://www.leeds.ac.uk

Funder(s)

Funder type Charity

Funder Name Cancer Research UK

Alternative Name(s) CR_UK, Cancer Research UK - London, CRUK

Funding Body Type Private sector organisation

Funding Body Subtype Other non-profit organizations

Location United Kingdom

Funder Name Takeda Pharmaceuticals International

Alternative Name(s) Takeda Pharmaceuticals International AG, Takeda Pharmaceuticals International GmbH

Funding Body Type Private sector organisation

Funding Body Subtype For-profit companies (industry)

Location Switzerland

Funder Name Celgene

Alternative Name(s) Celgene Corporation

Funding Body Type Private sector organisation **Location** United States of America

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 04/07/2022:

Data from this study will be published once trial endpoints have been reached and after the overall trial end date. Publication will be via peer-reviewed journals as well as via presentations at conferences. The results will also be available on UK cancer websites such as Myeloma UK and Cancer Research UK.

Previous publication and dissemination plan:

The protocol is not currently available. A protocol publication, based on the RADAR protocol will be available at a later date. Data from this study will be published once trial endpoints have been reached and after the overall trial end date. Publication will be via peer-reviewed journals as well as via presentations at conferences. The results will also be available on UK cancer websites such as Myeloma UK and Cancer Research UK.

Intention to publish date

31/08/2028

Individual participant data (IPD) sharing plan

De-identified individual participant data datasets generated and/or analysed during the current study will be available upon request from the Clinical Trials Research Unit, University of Leeds (contact CTRU-DataAccess@leeds.ac.uk in the first instance). Data will be made available at the end of the trial, i.e. usually when all primary and secondary endpoints have been met and all key analyses are complete. Data will remain available from then on for as long as CTRU retains the data.

CTRU makes data available by a 'controlled access' approach. Data will only be released for legitimate secondary research purposes, where the Chief Investigator, Sponsor and CTRU agree that the proposed use has scientific value and will be carried out to a high standard (in terms of scientific rigour and information governance and security), and that there are resources available to satisfy the request. Data will only be released in line with participants' consent, all applicable laws relating to data protection and confidentiality, and any contractual obligations to which the CTRU is subject. No individual participant data will be released before an appropriate agreement is in place setting out the conditions of release. The agreement will govern data retention, usually stipulating that data recipients must delete their copy of the released data at the end of the planned project.

The CTRU encourages a collaborative approach to data sharing and believes it is best practice for researchers who generated datasets to be involved in subsequent uses of those datasets. Recipients of trial data for secondary research will also receive data dictionaries, copies of key trial documents and any other information required to understand and reuse the released datasets.

The conditions of release for aggregate data may differ from those applying to individual participant data. Requests for aggregate data should also be sent to the above email address to discuss and agree on suitable requirements for release.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>		02/06/2022	08/06/2022	Yes	No
<u>HRA research summary</u>			28/06/2023	No	No