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

Submission date
27/11/2020

Recruitment status
No longer recruiting

Registration date
18/01/2021

Overall study status
Ongoing

Last Edited
04/03/2024

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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-ixazomib-lenalidomide-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
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Contact information

Type(s)
Scientific

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Type(s)
Public

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2018-003590-10

Integrated Research Application System (IRAS)
234453

ClinicalTrials.gov (NCT)
NCT03720041

Protocol serial number
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 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

Study type(s)
Treatment

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 score-adjusted 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
Phase III

Drug/device/biological/vaccine name(s)
Ixazomib, lenalidomide, dexamethasone

Primary outcome(s)
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

Key secondary outcome(s))
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

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) ≥ 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
4.1.2. Platelet count ≥50 x 10^9/l, or, in the case of heavy bone marrow infiltration (≥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 ≥30 x 10^9 /l is permitted. Please note: Platelet transfusions are not allowed ≤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 ≥50 x 10^9/l. Please note: Platelet transfusions are not allowed ≤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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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. ≥ 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. ≥ 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
United Kingdom

England

Scotland

Wales

Study participating centre
Royal Devon & Exeter Hospital
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Study participating centre
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Sandford Road
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Study participating centre
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Study participating centre
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Study participating centre
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TQ2 7AA

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King Edward Yard
Marlborough Hill
Bristol
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BS2 8HW

Study participating centre
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DE22 3NE

Study participating centre
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NW1 2BU

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

Study participating centre
Leicester Royal Infirmary
Aylestone Road
Leicester
United Kingdom
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Study participating centre
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Crownhill
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Study participating centre
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BN11 2DH

Study participating centre
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Spitafield Lane
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Study participating centre
The County Hospital
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United Kingdom
HR1 2BN

Sponsor information

Organisation
University of Leeds

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

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

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

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?
Protocol article		02/06/2022	08/06/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes