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Phase II study of the adjuvant use of lenalidomide in patients undergoing reduced intensity conditioning allogenic transplantation for multiple myeloma

Submission date
24/05/2011

Recruitment status
No longer recruiting

Registration date
24/05/2011

Overall study status
Completed

Last Edited
28/05/2020

Condition category
Cancer

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

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/trials-search/a-trial-looking-lenalidomide-after-stem-cell-transplant-for-people-with-myeloma-lenaric

Study website
http://www.birmingham.ac.uk/research/activity/mds/trials/crctu/trials/haematology/lenaric/index.aspx

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2009-012033-30

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7268

Study information

Scientific Title
Phase II study of the adjuvant use of lenalidomide in patients undergoing reduced intensity conditioning allogenic transplantation for multiple myeloma

Acronym
LenaRIC

Study objectives
Allogeneic stem cell transplant (SCT) remains the only curative option for multiple myeloma (MM). However, conventional (myeloablative) transplants remain associated with a substantial transplant related mortality which compromises effectiveness in younger patients and precludes their use entirely in patients over the age of 55 years. The recent demonstration that the use of reduced intensity conditioning (RIC) regimens substantially reduces the toxicity of allografting, whilst permitting durable donor stem cell engraftment, has raised the hope of extending this procedure to many patients who would currently not be considered for transplantation. Donor lymphocytes can be safely administered in patients who relapse late after transplantation. Routine use of donor lymphocyte infusion (DLI) early after transplant is generally avoided, as the risk of GVHD increases the sooner DLI is administered after transplant. In the context of myeloma, the strategy of delayed DLI (at one year) reduces the risk of GVHD. Consequently, an independent anti-myeloma strategy early after transplantation is required to allow sufficient delay before DLI can be safely administered. The tolerability and remarkable activity of lenalidomide against myeloma makes it an excellent candidate to be used in an adjunctive role early after a reduced intensity regimen transplant prior to later institution of DLI, to suppress the growth and rapid recovery of a residual myeloma cell population

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 12/11/2010, ref 10/H1208/49

Study design
Non-randomised interventional trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)

Hospital

Study type(s)
Treatment

Participant information sheet
http://www.birmingham.ac.uk/research/activity/mds/trials/crctu/trials/haematology/lenaric/investigators.aspx

Health condition(s) or problem(s) studied
Haematological Oncology, Myeloma

Interventions
Patients will receive up to 12 cycles of Lenalidomide (or until 12 months post-transplant). Each cycle will last 28 days and patients will receive Lenalidomide on days 1 - 21 of each 28 day cycle. Dose reductions are in place. Follow up length: 24 month(s). Study entry : registration only.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Fludarabine, lenalidomide, ciclosporin, ATG

Primary outcome measure
1. Progression free survival at 2 years post transplant
2. Timepoint(s): 2 years post transplant

Secondary outcome measures
1. Day +100 and 1 year non-relapse mortality, timepoint(s): day 100 and year 1
2. Disease free survival at 1 and 2 years post transplant, timepoint(s): Markers of disease assessed at months 1, 3, 6, 9, 12, 15, 18, 21 and 24 post transplant
3. Donor engraftment, timepoint(s): lineage-specific chimerism assessed at months 1, 3, 6, 9, 12, 15, 18, 21 and 24 post-transplant
4. GVHD, timepoint(s): GVHD will be monitored continuously until 2 years post transplant
5. Overall survival at years 1 and 2 post transplant, timepoint(s): will be monitored continuously until 24 months post-transplant

Overall study start date
01/05/2011

Completion date
19/12/2017

Eligibility

Key inclusion criteria

1. Multiple myeloma subjects who have received a high dose melphalan conditioned autologous transplant in the preceding 120 days and who are in CR1/2 or VGPR1/2 as defined by International uniform response criteria for Myeloma, 2006 (Appendix 1)
2. Patients 18 to 70 years in whom allogeneic transplantation using a reduced intensity conditioning regimen is not contra-indicated but who are not suitable for conventional allograft
3. Eastern Cooperative Oncology Group (ECOG) status <2 or an ECOG status of 3 if the reason for a status of 3 is due exclusively to multiple myeloma (e.g. pathological fracture) (Appendix 2)
4. Patients with a HLA identical sibling or ten/ten antigen (A,B,C,DR,DQ) matched unrelated donor
5. Cardiac ejection fraction > 40%
6. Measured EDTA Creatinine clearance >50 ml/min
7. Carbon Monoxide Diffusing Capacity (DLCO) >50%
8. Liver function (AST or ALT) < 2.5 x upper limit of normal
9. Patients able to give written informed consent prior to allogeneic transplant, with the understanding that the patient has the right to withdraw from the study at any time, without prejudice
10. Patients willing and able to comply with the protocol for the duration of the study
11. Agree to abstain from donating blood (and semen in male subjects) while taking study drug therapy and for 28 days following discontinuation of study drug therapy
12. Agree not to share study drug with another person and to return all unused study drug to the investigator or pharmacist
13. Male or female
14. Upper age limit 70 years
15. Lower age limit 18 years

Updated 10/07/2017: upper age limit changed from 65 to 70 years.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 patients

Total final enrolment
40

Key exclusion criteria
1. Patients with allergies or contraindications to receiving Fludarabine, Lenalidomide, ciclosporin or ATG
2. Pregnant or lactating women
3. Adults of reproductive potential not willing to comply with the Lenalidomide Risk Minimisation Plan

4. Patients with organ allografts
5. Any co-morbidity that, in the investigators opinion, would affect the patients participation in this study
6. Patient who have taken any other investigational medical product within 4 weeks of starting conditioning therapy

Added 10/07/2017:
7. Patients with known positive serology for HIV/Hepatitis B/Hepatitis C
8. Patients who have undergone a previous allogeneic stem cell transplant
9. Patients who have previously progressed on Lenalidomide

Date of first enrolment
31/05/2011

Date of final enrolment
12/06/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Elizabeth Hospital
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
University Hospitals Birmingham NHS Foundation Trust (UK)

Sponsor details
c/o Miss Shamyla Siddique
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Sponsor type
University/education

Website
http://www.uhb.nhs.uk/

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK Feasibility Study Committee

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
Celgene Ltd (unrestricted educational grant)

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal late 2017 – early 2018.

Intention to publish date
19/03/2018

Individual participant data (IPD) sharing plan
The current 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?
Basic results			28/05/2020	No	No
HRA research summary			28/06/2023	No	No