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FLAMSA-BU conditioning regimen in patients with acute myeloid leukaemia and myelodysplasia undergoing allogeneic stem cell transplantation

Submission date
11/10/2013

Recruitment status
No longer recruiting

Registration date
11/10/2013

Overall study status
Completed

Last Edited
12/05/2022

Condition category
Cancer

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

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-different-combinations-of-drugs-before-a-stem-cell-transplant-for-aml-or-mds-figaro

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2012-005538-12

Protocol serial number

14772

Study information

Scientific Title
A randomised trial of the FLAMSA-BU conditioning regimen in patients with acute myeloid leukaemia and myelodysplasia undergoing allogeneic stem cell transplantation

Acronym
FIGARO

Study objectives
This is a prospective, phase II, multicentre, randomised clinical trial in patients with acute myeloid leukaemia (AML) or myelodysplasia (MDS) undergoing reduced intensity conditioning (RIC) allogeneic stem cell transplantation (SCT) comparing the novel conditioning regimen (fludarabine/cytarabine/amsacrine/busulphan/ATG) (FLAMSA-BU) with standard conditioning regimens fludarabine/melphalan/alemtuzumab (FMA), fludarabine/busulphan/alemtuzumab (FBA) or fludarabine/busulphan/ATG (FB-ATG).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber Sheffield, 03/06/2013, ref: 13/YH/0152

Study design
Randomised interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Haematological Oncology; Disease: Leukaemia (acute myeloid)

Interventions
Patients will be stratified at randomisation by their underlying disease (AML; MDS), cytogenetic risk group (adverse risk; intermediate or good risk), disease status at transplant [1st complete remission (CR1) or 2nd complete remission (CR2)]; primary refractory disease, intended control arm regimen (FMA; FBA; FB-ATG), age (above; below 60 years of age) and by donor type (sibling; unrelated).

Patients eligible for entry into the trial will be randomised on a 1:1 basis

Standard conditioning regimens fludarabine/melphalan/alemtuzumab (FMA), fludarabine /busulphan/alemtuzumab (FBA) or fludarabine/busulphan/ATG (FB-ATG).

Novel conditioning regimen, Using fludarabine, cytarabine, amsacrine, busulphan and ATG combined to condition the patients for a reduced intensity stem cell transplant.

The interventions are from 7 to 12 days depending in which treatment arm is selected. The follow-up is 24 months for both arms.

Study Entry : Single Randomisation only

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Fludarabine, cytarabine, amsacrine, busulphan

Primary outcome(s)
Overall survival, measured using date of death from any cause; Timepoints: 24 months post transplant

Key secondary outcome(s)
1. Disease relapse, measured using date of relapse; Timepoint(s): Disease relapse within the 24 month follow up
2. Event free survival, measured using date of relapse or date of death; Timepoint(s): 24 months post transplant
3. Incidence of graft versus host disease (GvHD), measured counting episodes of GvHD; Timepoint(s): Throughout the 24 month follow up
4. Quality of Life; Timepoint(s): FACT-BMT questionnaire, completed pre-tranplant, at day 42 and month 3, 6, 9, 12, 18 and 24.
5. Transplant related mortality measured by any death related to transplant procedure, not underlying, disease at day 100 and 12 months post-transplant

Completion date
31/10/2015

Eligibility

Key inclusion criteria
1. Patients with a morphologically documented diagnosis of AML or MDS clinically indicated to receive a RIC allograft with one the following disease characteristics:
AML
1.1. Patients in 1st complete remission (CR1) with adverse risk cytogenetics
1.2. Patients in 2nd complete remission (CR2)
1.3. Patients with primary refractory AML defined as the failure to achieve a morphological remission after 2 courses of induction chemotherapy
1.4. Patients participating in the UK NCRN AML17 (or the subsequent AML19) clinical trial who have been defined as high risk (based upon age, de novo or secondary disease, cytogenetics, white blood count, sex and response to course 1)
1.5. Patients participating in the UK NCRN AML17, AML18 (or the subsequent AML19) clinical trials who have been defined as high risk by Minimal Residual Disease (MRD) criteria

MDS
1.6. Patients with advanced MDS (defined by an IPSS score of INT1 with >5% blasts or INT2 or high risk) who have < 5% blasts at the time of randomisation following chemotherapy or hypomethylating agents if necessary
2. Patients aged ≥ 16 years
3. Patients with an HLA identical sibling or suitable matched unrelated donor (suitable match defined as no greater
than a single allele mismatch at HLA A, B, C or DRB1)
4. Patients considered suitable to undergo a reduced intensity conditioned allogeneic stem cell transplant as clinically judged by the Local Investigator including:
4.1. Adequate cardiac, pulmonary, hepatic and renal function as determined by pre-transplant assessments
4.2. Resolution of any toxic effects of prior therapy (including radiotherapy, chemotherapy or surgical procedures)
5. Patients with an ECOG performance status of 0, 1 or 2
6. Patients have given written informed consent
7. Patients willing and able to comply with scheduled study visits and laboratory tests

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
244

Key exclusion criteria
1. Patients with chemorefractory relapse of AML or MDS
2. Patients with contraindications to receiving RIC allogeneic SCT
3. Female patients who are pregnant or breastfeeding. All women of childbearing potential must have a negative pregnancy test before commencing treatment
4. Adults of reproductive potential not willing to use appropriate, effective, contraception during the specified period
5. Patients with clinically significant cardiac disease (New York Heart Association, Class III or IV)
6. Patients with renal or hepatic impairment as clinically judged by Local Investigator
7. Patients with active infection, HIV positive or chronic active Hep A, B, C
8. Patients with concurrent active malignancy

Date of first enrolment
10/10/2013

Date of final enrolment
31/10/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Birmingham
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Sponsor information

Organisation
University of Birmingham (UK)

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Leukaemia and Lymphoma Research; Grant Codes: 12071

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2021	12/05/2022	Yes	No
Abstract results	Presented at ASH	13/11/2019	12/05/2022	No	No
Basic results		23/01/2022	12/05/2022	No	No
HRA research summary			28/06/2023	No	No
Plain English results		10/05/2022	12/05/2022	No	Yes