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Adjunctive use of azacitidine in patients with acute myeloid leukaemia (AML) or myelodysplasia (MDS) undergoing a reduced intensity conditioned allogeneic transplant

Submission date
13/02/2008

Recruitment status
No longer recruiting

Registration date
20/03/2008

Overall study status
Completed

Last Edited
04/04/2022

Condition category
Cancer

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

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-study-looking-new-chemotherapy-after-transplant-for-acute-myeloid-leukaemia-ricaza

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
RG 07-187

Study information

Scientific Title
Phase ll study of the adjunctive use of azacitidine in patients undergoing reduced intensity allogeneic transplantation in acute myeloid leukaemia and myelodysplasia

Acronym
RICAZA

Study objectives
Disease relapse is the major cause of treatment failure after allogeneic transplantation using reduced intensity conditioning (RIC) regimens in patients with acute myeloid leukaemia (AML) or myelodysplasia (MDS) and therefore strategies which reduce the risk of disease relapse are required. Although there has been interest in the use of prophylactic donor lymphocyte infusions (DLI) to reduce the risk of relapse, their use is associated with a significant risk of severe graft-versus-host disease (GVHD) when administered early post-transplant. Azacitidine has potent activity against malignant myeloid progenitors and this study aims to examine whether its administration post-transplant can modify the kinetics of disease relapse after a RIC allograft for AML or MDS thereby postponing or eliminating the requirement for DLI.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands Research Ethics Committee on 24/04/2008 (ref: 08/H1208/4)

Primary study design
Interventional

Study design
Phase II, multicentre, single arm, open-label, non-randomised study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute myeloid leukaemia (AML) or myelodysplasia (MDS)

Interventions
All participants will receive azacitidine administered six weeks after undergoing reduced intensity conditioned allogeneic transplantation. Azacitidine will be administered subcutaneously for 5 days for 10 cycles (each cycle being 28 days) at a dose of 36 mg/m^2.

Total duration of trial treatment: 11 months; follow up period: 24 months.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Azacitidine

Primary outcome(s)
Safety of azacitidine treatment. Adverse events and therapy-related side effects will be monitored continuously during azacitidine treatment and until 28 days after the last dose.

Key secondary outcome(s)
1. Relapse rate, assessed at 12 months post-transplant
2. Survival, assessed annually until 3 years post-transplant

Completion date
31/05/2011

Eligibility

Key inclusion criteria
1. Patients (male and female) between the age of 18 - 65 years in whom allogeneic transplantation using a myeloablative conditioning regimen is contra-indicated
2. Patients who fulfill the World Health Organization (WHO) criteria for AML or MDS
3. Patients with a human leukocyte antigen (HLA) identical sibling or suitable matched unrelated donor
4. Must give written informed consent and be able to comply with the protocol for the duration of the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
37

Key exclusion criteria
1. Patients with contra-indications to receiving fludarabine or azacitidine
2. Pregnant or lactating women or adults of reproductive potential not willing to use appropriate medically approved contraception during the trial and for 12 months post-azacitidine
3. Any co-morbidity that in the investigators opinion will affect the patients participation in this study

Date of first enrolment
01/06/2008

Date of final enrolment
31/05/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Centre for Clinical Haematology
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
University of Birmingham (UK)

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Industry

Funder Name
Pharmion (UK)

Funder Name
University of Birmingham (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

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	results	05/04/2012		Yes	No
Plain English results			04/04/2022	No	Yes