ISRCTN32336114 https://doi.org/10.1186/ISRCTN32336114

A phase II trial of sequential treatment with cytoreductive therapy and reduced intensity conditioning allogeneic stem cell transplantation for relapsed/ refractory acute myeloid leukemia, high risk myelodysplasia, or other high risk myeloid malignancies

Submission date
09/02/2007

Recruitment status
No longer recruiting

Registration date
27/03/2007

Overall study status
Completed

Last Edited
31/03/2022

Condition category
Cancer

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

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-low-intensity-stem-cell-transplant-after-chemotherapy-acute-myeloid-leukaemia-high-risk-myelodysplastic-syndrome-MUNICH

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

2007-000806-64

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BLT004973

Study information

Scientific Title
A phase II trial of sequential treatment with cytoreductive therapy and reduced intensity conditioning allogeneic stem cell transplantation for relapsed/ refractory acute myeloid leukemia, high risk myelodysplasia, or other high risk myeloid malignancies

Acronym
Sequential treatment with cytoreductive therapy & transplant

Study objectives
Is it safer and more effective, in treating high risk myeloid malignancies, to immediately follow chemotherapy with allogeneic haemopoietic stem cell transplantation than to treat in two distinct phases, with a break to determine remission status?

Ethics approval required
Old ethics approval format

Ethics approval(s)
East London and The City Committee 1, 23/07/2007, ref: 07/Q0603/65

Study design
Open phase II study

Primary study design
Interventional

Secondary study design
Non randomised study

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

Myeloid malignancies

Interventions
Reduced intensity conditioning allogeneic stem cell transplantation: standard practice calls for remission (or near remission) in patients treated with chemotherapy before progression to transplantation. This occurs in less than 50% of cases. In this study, all patients will proceed straight to transplantation.

Intervention Type
Biological/Vaccine

Phase
Phase II

Primary outcome measure
Overall Survival (OS) at 1, 2 and 4 years

Secondary outcome measures
1. Event Free Survival (EFS) at 1, 2 and 4 years
2. Treatment Related Mortality (TRM) at d100, 1 and 2 years and cause of mortality
3. Incidence and Grade of Acute Graft versus Host Disease (GVHD)
4. Incidence and Grade of Chronic GVHD
5. Time to Engraftment*
6. Full Split Chimerism at Days 30, 60, 100 and 1 year
7. Request for Donor Lymphocyte Infusion (DLI) (Mixed chimerism vs disease persistence)
8. Incidence of opportunistic infections
9. Duration of hospitalisation
*Date of Neutrophil Engraftment is defined as the first of two consecutive days with a neutrophil count exceeding 500/µL. Date of platelet recovery is considered the first of three consecutive days with an unsupported platelet count exceeding 20 x 109 / L.

Overall study start date
01/04/2007

Completion date
01/04/2011

Eligibility

Key inclusion criteria
1. Diagnosis of histologically documented acute myeloid leukemia (AML) (any WHO type), with primary induction failure, or at relapse where the patient is not a candidate or does not wish to proceed to a myeloablative transplant. Also, histologically / cytogenetically documented diagnosis of Myelodysplasia (MDS) (IPSS Int. 2, HR) , or other high risk Myeloid Malignancy where the patient is not a candidate or does not wish to proceed to a myeloablative transplant.
2. All acute toxic effects of any prior radiotherapy, chemotherapy, or surgical procedures must have resolved to National Cancer Institute (NCI) Common Toxicity Criteria (CTC) (Version 3.0) Grade < 2 (with the exception of chemotherapy–induced alopecia). Surgery must have occurred at least 21 days prior to initiation of treatment.
3. Age must be greater than 18 years.

4. Last dose of antineoplastic therapy must be more than 14 days from starting treatment, except for hydroxyurea or Low Dose Ara C which may have been administered up to 24 hours prior to first study drug administration for leukoreduction.
5. Eastern Cooperative Oncology Group (ECOG) performance status must be 0, 1, or 2.
6. Life expectancy of at least 2 months.
7. Pregnancy test (females of childbearing potential) Negative.
8. Signed informed consent indicating that they are aware of the neoplastic nature of their disease and have been informed of the procedures to be followed, alternatives, potential benefits, side effects, risks, and discomforts.
9. Willing and able to comply with scheduled visits, treatment plan, and laboratory tests.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
93

Total final enrolment
54

Key exclusion criteria
1. Concurrent therapy with any other investigational agent.
2. Pregnant or breastfeeding women. All at-risk female subjects must have a negative pregnancy test within 10 days prior to the start treatment.
3. Clinically significant cardiac disease (New York Heart Association, Class III or IV).
4. Dementia or altered mental status that would prohibit informed consent.
5. Other severe, acute, or chronic medical or psychiatric condition or laboratory abnormality that may increase the risk associated with study participation or may interfere with the interpretation of study results and, in the judgment of the investigator, would make the subject inappropriate for this study.
6. Current malignancies at other sites, with the exception of adequately treated cone–biopsied in situ carcinoma of the cervix uteri and basal or squamous cell carcinoma of the skin. Cancer survivors, who have undergone potentially curative therapy for a prior malignancy, have no evidence of that disease for five years and are deemed at low risk for recurrence, are eligible for the study.

Date of first enrolment
01/04/2007

Date of final enrolment
01/04/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Bartholomew's Hospital
London
United Kingdom
EC1A 7BE

Sponsor information

Organisation
Barts and the London NHS Trust (UK)

Sponsor details
The Joint Research Office
3rd Floor Rutland House
42–46 New Road
Whitechapel
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England
United Kingdom
E1 2AX

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Government

Funder Name
Barts and the London NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Basic results				No	No
Plain English results			31/03/2022	No	Yes