

# 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

<b>Submission date</b> 09/02/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/03/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/03/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

### Contact name

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### Contact details

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## Additional identifiers

Clinical Trials Information System (CTIS)

2007-000806-64

**Protocol serial number**

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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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/ $\mu$ L. Date of platelet recovery is considered the first of three consecutive days with an unsupported platelet count exceeding  $20 \times 10^9 / L$ .

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

**St Bartholomew's Hospital**

London

United Kingdom

EC1A 7BE

**Sponsor information**

## Organisation

Barts and the London NHS Trust (UK)

## ROR

<https://ror.org/00b31g692>

## Funder(s)

### Funder type

Government

### Funder Name

Barts and the London NHS Trust (UK)

## 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?
<a href="#">Basic results</a>				No	No
<a href="#">Plain English results</a>			31/03/2022	No	Yes