

# Supplementary Study for Patients With Invasive Fungal Infection, Entered Into AML 11, AML 12 and UKALL XII or Their Successors

<b>Submission date</b> 19/08/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 31/10/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr - -

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G8223452 - MRC IFI

# Study information

## Scientific Title

Supplementary Study for Patients With Invasive Fungal Infection, Entered Into AML 11, AML 12 and UKALL XII or Their Successors

## Study objectives

To assess the effect of GM-CSF on the outcome of fungal infection after treatment for leukaemia

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Not Specified

## Participant information sheet

## Health condition(s) or problem(s) studied

Leukaemia (acute)

## Interventions

1. Arm A: Placebo given by subcutaneous injection plus liposomal amphoterecin (AmBisome) at a dose of 3 mg/Kg per day by intravenous infusion for those with proven infection and 1 mg/Kg per day by intravenous infusion for those with suspected infection.

2. Arm B: GM-CSF at an initial dose of 5 µg/Kg/day by subcutaneous injection plus liposomal amphoterecin (AmBisome) at an initial dose of 3 mg/Kg/day by intravenous infusion for those with proven infection and 1 mg/Kg/day by intravenous infusion for those with suspected infection.

## Intervention Type

Other

## Phase

Not Specified

**Primary outcome measure**

1. Resolution of fever
2. Resolution of radiological and microbiological signs of infection

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/06/1997

**Completion date**

30/06/1997

## **Eligibility**

**Key inclusion criteria**

1. Patients entered into the MRC trials AML 11, AML 12, or UKALL XII, or their successors
2. The following classification of fungal infection in leukaemia patients eligible for this trial are
  - a. Pulmonary fungal infection - proven or suspected
  - b. Sinus infected - proven or suspected
  - c. Fungemia - suspected
  - d. Chronic hepatosplenic candidosis - proven by Computed Tomography (CT)/Magnetic Resonance Imaging (MRI)
  - e. Invasive cutaneous infection - proven
  - f. Cerebral fungal infection - proven or suspected
3. Karnofsky performance status of at least 30%
4. Patients with known intolerance to either test drug are excluded
5. Previous use of AmBisome within 2 weeks, or use of granulocyte-macrophage colony-stimulating factor (GM-CSF) within 3 months excludes a patient
6. Life expectancy of >6 weeks
7. Aged >15 years

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

200

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/06/1997

**Date of final enrolment**

30/06/1997

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

## Sponsor information

**Organisation**

Medical Research Council (MRC) (UK)

**Sponsor details**

20 Park Crescent

London

United Kingdom

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+44 (0)20 7636 5422

clinical.trial@headoffice.mrc.ac.uk

**Sponsor type**

Research council

**Website**

<http://www.mrc.ac.uk>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Medical Research Council (MRC) (UK)

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

Norvartis Pharmaceuticals (UK)

**Funder Name**

Nexstar Pharmaceuticals (UK)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration