

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

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 31/10/2019	Condition category 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
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Additional identifiers

Protocol serial number
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

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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**

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Medical Research Council (MRC) (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, Medical Research Committee and Advisory 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration