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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 31/10/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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
W1B 1AL
+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