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Acute Myeloid Leukaemia - High Risk (AML-HR)

Submission date 25/10/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/10/2000	**Overall study status** Completed	
Last Edited 17/10/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00005863

Secondary identifying numbers
G9800529

Study information

Scientific Title
Acute Myeloid Leukaemia - High Risk (AML-HR)

Acronym
AML-HR

Study objectives
To improve the outcome of patients with high risk AML by randomised evaluation of:
1. The standard ADE (Ara-C,daunorubicin, etoposide) reinduction regimen versus the newer FLA (fludarabine, high-dose Ara-C) regimen
2. The addition of growth factor (G-CSF) during and after chemotherapy.
3. The addition of retinoic acid (ATRA) during and after chemotherapy. Patients may be entered into all three randomisations, any combination of two randomisations, or just one randomisation. The therapeutic relevance of morphology, genetics and other features will also be investigated.

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)
Hospital

Study type(s)
Not Specified

Participant information sheet

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

Interventions
Three randomised comparisons:
1. ADE versus FLA
2. Granulocyte Colony Stimulating Factor (G-CSF) versus control
3. All-trans-retinoic acid (ATRA) versus control

Follow-up until death.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Survival
2. Complete remission (CR) rates and reason for failure
3. Duration of remission
4. Toxicity
5. Quality of life
5. Supportive care requirements

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/1998

Completion date
31/12/2004

Eligibility

Key inclusion criteria
1. High risk acute myeloid leukaemia (AML) (de novo or secondary, except acute promyelocytic leukemia [APL])
2. Suitable for intensive therapy
3. Informed consent given. High risk AML is defined as:
(a) Resistant disease (greater than 15% blasts in bone marrow) after one induction course
(b) Refractory disease (ie not in complete remission [CR]) after two or more induction courses
(c) Relapse from first CR (with more than 5% blasts in bone marrow)
(d) In complete or partial remission after one induction course but with adverse cytogenic abnormalities at diagnosis

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
600

Key exclusion criteria
1. APL
2. Concurrent active malignancy
3. Blast transformation of CML
4. Relapse from second or greater CR
5. Severe renal impairment (creatinine clearance less than 30 millilitres per minute)
6. Pregnant, lactating or potentially fertile and not taking adequate contraceptive precautions

Date of first enrolment
01/11/1998

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Haematology
Birmingham
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Sponsor information

Organisation
Medical Research Council (MRC) (UK)

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Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results				No	Yes
Results article	Results	15/06/2006		Yes	No