

Acute Myeloid Leukaemia - High Risk (AML-HR)

Submission date 25/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/10/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/10/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00005863

Protocol serial number
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

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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 cytogenetic abnormalities at diagnosis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

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

United Kingdom

England

Study participating centre

Department of Haematology

Birmingham

United Kingdom

B9 5SS

Sponsor information

Organisation

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

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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?
Results article	Results	15/06/2006		Yes	No
Plain English results				No	Yes