# Acute Myeloid Leukaemia - High Risk (AML-HR)

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

### Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr DW Milligan

#### Contact details

Department of Haematology Birmingham Heartlands Hospital Bordesley Green East Birmingham United Kingdom B9 5SS +44 (0)121 424 3699 d.w.milligan@bham.ac.uk

# 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 United Kingdom B9 5SS

# 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

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