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# AML 12 - Acute myeloid leukaemia Adults (modified)

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 25/10/2000 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 25/10/2000 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 25/07/2019 | Cancer | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof AK Burnett

**Contact details**
Department of Haematology
University of Wales College of Medicine
Heath Park
Cardiff
United Kingdom
CF14 4XN
+44 (0)29 2074 2375
burnettak@cardiff.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
G8223452

# Study information

### Scientific Title
AML 12 - Acute myeloid leukaemia Adults (modified)

### Acronym
AML 12

### Study objectives
To improve the outcome of patients with newly diagnosed AML by randomised evaluation of:

1. Standard dose (100 mg/m2 b.d.) versus higher dose (200mg/m2 b.d.) Ara-C within a DAT (daunorubicin, Ara-C, thioguanine) induction regimen (courses 1 and 2)
2. The addition of retinoic acid (ATRA) during and after induction chemotherapy (courses 1 and 2)
3. Four versus five courses of therapy in total (where the final course is either chemotherapy or transplant)
4. Bone marrow transplantation (BMT) (either allogenic or autologous) versus conventional chemotherapy as the final course (good risk patients should not be entered into this randomisation).

The therapeutic relevance of morphology, cytogenetics, molecular genetics and immunophenotype 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)
Treatment

### Participant information sheet

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

### Interventions

Four randomised comparisons:
1. S-DAT versus H-DAT
2. All-trans retinoic acid (ATRA) versus control
3. 4 versus 5 courses of therapy in total
4. Bone Marrow Transplant (BMT) versus chemotherapy as the final course

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
Survival; complete remission (CR) rates and reason for failure; duration of remission; toxicity; quality of life; supportive care requirements.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/10/1994

### Completion date
01/01/2001

## Eligibility

### Key inclusion criteria
1. Acute myeloid leukaemia (AML) (any type of de novo or secondary AML, including acute promyelocytic leukemia [APL])
2. Suitable for intensive therapy
3. Normally under the age of 60 years (but older patients can be entered if considered suitable)
4. Informed consent given

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
Not provided at time of registration

### Key exclusion criteria
1. Previous cytotoxic therapy for leukaemia
2. Concurrent active malignancy
3. Blast transformation of CML

4. Pregnant or lactating
5. Intensive chemotherapy not considered to be an appropriate treatment option
6. Patients with APL are not eligible for the ATRA randomisation

### Date of first enrolment
01/10/1994

### Date of final enrolment
01/01/2001

## Locations

### Countries of recruitment
United Kingdom

Wales

### Study participating centre
**Department of Haematology**
Cardiff
United Kingdom
CF14 4XN

## 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 (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

# 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 | 15/09/2001 | | Yes | No |
| Results article | results | 15/11/2005 | | Yes | No |
| Results article | results | 04/02/2010 | | Yes | No |
| Results article | results | 01/04/2013 | | Yes | No |
| Results article | results | 10/07/2014 | | Yes | No |
| Results article | results | 01/01/2018 | 25/07/2019 | Yes | No |