

# AML 12 - Acute myeloid leukaemia Adults (modified)

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>25/10/2000   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>25/10/2000 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>25/07/2019       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data                                              |

**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

**Protocol serial number**  
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/m<sup>2</sup> b.d.) versus higher dose (200mg/m<sup>2</sup> 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

## **Study type(s)**

Treatment

## **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(s)**

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

**Key secondary outcome(s)**

Not provided at time of registration

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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)

## 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, 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? |
|---------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>       | results | 15/09/2001   |            | Yes            | No              |
| <a href="#">Results article</a>       | results | 15/11/2005   |            | Yes            | No              |
| <a href="#">Results article</a>       | results | 04/02/2010   |            | Yes            | No              |
| <a href="#">Results article</a>       | results | 01/04/2013   |            | Yes            | No              |
| <a href="#">Results article</a>       | results | 10/07/2014   |            | Yes            | No              |
| <a href="#">Results article</a>       | results | 01/01/2018   | 25/07/2019 | Yes            | No              |
| <a href="#">Plain English results</a> |         |              |            | No             | Yes             |