

AML 12 - Acute myeloid leukaemia Adults (modified)

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 25/07/2019	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

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/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

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?
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
Plain English results				No	Yes