ISRCTN17833622 https://doi.org/10.1186/ISRCTN17833622

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

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, 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