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Acute Myeloid Leukaemia (AML) Trial 12 (modified) for patients aged under 60

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 19/08/2002	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 30/05/2012	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/aml12-trial-different-chemotherapy-regimes-in-the-treatment-of-acute-myeloid-leukaemia

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MRC AML12 (modified)

Study information

Scientific Title

Study objectives

Added as of 07/03/2007:
To compare two methods of administering all-Trans Retinoic Acid (ATRA) to patients with acute promyelocytic leukaemia (APL, FAB AML-M3) - either ATRA for 5 days only before the introduction of trial induction chemotherapy or continuous ATRA during induction chemotherapy until complete remission is achieved (or for a maximum of 60 days) with respect to differences in haemorrhagic complications, induction deaths, remission rate, remission duration and overall survival. To evaluate the role of ATRA in correcting the coagulopathy associated with APL. - To investigate the two methods of using ATRA therapy with respect to the sequence of change of laboratory parameters of coagulation and thrombolysis, and blood product usage. To evaluate cytogenetic and molecular monitoring of disease status with reference to the prediction of morphological leukaemia relapse.

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 (acute)

Interventions
Four randomised comparisons:

At diagnosis:
1. S-DAT versus H-DAT
2. All-trans-retinoic acid (ATRA) versus not (except for acute promyelocytic leukaemia (APL) patients who will receive ATRA)

After course 3:
3. 4 versus 5 courses of total therapy
4. Bone marrow transplant (BMT) versus chemotherapy as the final course of therapy

Added 08/09/09: A trial with 250 patients would have a power of 50% to detect (at 2p=0.05) a 10% absolute difference in remission rate or long term survival between the two ATRA groups. If no difference were apparent between the two arms the possibility that one arm is greatly superior to the other (ie more than 50% better) would be eliminated. With extended collaboration (UK and internationally) to recruit a total of 500 patients the trial would have a power of about 90% to detect a 10% difference in remission rate and a power of about 50% to detect a 5% difference.

Intervention Type

Other

Phase
Not Specified

Primary outcome(s)
Added as of 07/03/2007:
Haemorrhagic complications, induction deaths, remission rate, remission duration, overall survival and the role of ATRA in correcting the coagulopathy associated with APL.

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/11/2003

Eligibility

Key inclusion criteria
1. Have one of the forms of AML
2. Are considered suitable for intensive chemotherapy
3. Are normally under the age of 60 years, but can be older as long as intensive therapy is considered suitable
4. Have given written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
Added as of 07/03/2007:
1. Previously received any treatment for APL
2. Other forms of AML (including CML in promyelocytic blast crisis)
3. Another concurrent active malignancy
4. Pregnant or consider the possibility of becoming pregnant during the course of treatment

Date of first enrolment
01/11/1998

Date of final enrolment
01/11/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

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 on FLT3 duplication as a prognostic risk factor in chemotherapy	15/09/2001		Yes	No
Results article	results on relationships between age at diagnosis, clinical features, and outcome of therapy	15/09/2001		Yes	No
Results article	results	15/11/2005		Yes	No
Results article	results	01/03/2006		Yes	No
Results article	results	01/02/2010		Yes	No
Other publications	pooled analysis of prognostic significance of rare recurring chromosomal abnormalities	22/07/2010		Yes	No