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Acute myeloid leukaemia (AML) trial 12 (protocol for children)

Submission date 25/10/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/10/2000	**Overall study status** Completed	
Last Edited 14/01/2009	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00003436

Secondary identifying numbers
G8223452

Study information

Scientific Title

Acronym
AML 12

Study objectives
To compare two induction schedules (ADE and MAE) with respect to achievement and duration of remission, survival, toxicity and supportive care requirements; to compare four versus five course of treatment in total (where the final course is either chemotherapy or BMT) with respect to remission duration, relapse rates, deaths in remission and overall survival, to compare the value of allogeneic BMT vs. conventional chemotherapy with respect to remission duration, relapse rates, death in remission and overall survival, to reduce toxicity without compromising survival by restricting the number of patients receiving BMT.
To evaluate the therapeutic relevance of morphological, cytogenetic, molecular-genetic and immunophenotype assessments, quality of life assessment and economic evaluation and monitoring cardiac function with observation at trial entry, prior to each antracycline /anthracenedione-containing course, prior to allograft and within 4 weeks of the end of therapy.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Interventions
ADE/MAE

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Achievement and duration of remission, survival, febrile incidents, toxicity including cardiotoxicity, supportive care requirements and long-term outcome.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/1995

Completion date
01/01/2002

Eligibility

Key inclusion criteria
1. They have one of the types of acute myeloid leukaemia (de novo or secondary)
2. They have aggressive myelodysplastic syndrome (MDS) (Refractory anemia with excess blasts [RAEB], Refractory anemia with excess blasts in transformation [RAEB-t]) for whom AML-type therapy is considered appropriate
3. They are considered suitable for intensive chemotherapy
4. They are under 16 years and if the patients/parents have given informed consent

Participant type(s)
Patient

Age group
Child

Upper age limit
16 Years

Sex
Both

Target number of participants
2,000

Key exclusion criteria
1. Patients who have previously received cytotoxic chemotherapy for leukaemia;
2. They are in blast transformation of chronic myeloid leukaemia;
3. They have a concurrent active malignancy or the physician and patient/parents consider that intensive therapy is not an appropriate option.

Date of first enrolment
01/04/1995

Date of final enrolment
01/01/2002

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Department of Haematology
Glasgow
United Kingdom
G3 8SJ

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (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?
Results article	results	01/12/2005		Yes	No