

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

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 14/01/2009	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

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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 anthracycline /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

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Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

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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