UKALL R2 - Acute Lymphoblastic Leukaemia trial

Submission date [] Prospectively registered Recruitment status 06/04/2000 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 06/04/2000 Completed [X] Results [] Individual participant data Last Edited Condition category 04/10/2007 Cancer

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers G8223452

Study information

Scientific Title

Acronym

UKALL R2

Study objectives

To compare continuing chemotherapy with unrelated donor BMT in relapsed childhood ALL following a common re-induction and consolidation regimen.

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)

Hospital

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Acute Lymphoblastic Leukaemia

Interventions

Continuing chemotherapy/unrelated donor BMT

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Survival, disease free survival

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/02/1995

Completion date

30/09/2008

Eligibility

Key inclusion criteria

They are children under 15 years at original diagnosis and treated on UKALL trials or pilot studies with first relapse less than 4 years from the start of treatment of ALL at any site and no suitable related bone marrow treatment (BMT) donor is available

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

200 - Closed to recruitment - in long term follow-up

Key exclusion criteria

- 1. They are multiply relapsed patients
- 2. They have a prior history of toxicity or organ damage such that completion of the protocol is felt unlikely at the outset
- 3. They have had an isolated CNS or testicular relapse more than 6 months off treatment.

Date of first enrolment

01/02/1995

Date of final enrolment

30/09/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre The Children's Hospital

Birmingham United Kingdom B16 8ET

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

20 Park Crescent London United Kingdom W1B 1AL +44 (0)20 7636 5422 clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

http://www.mrc.ac.uk

Funder(s)

Funder type

Research council

Funder Name

UK Medical Research Council

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	01/07/2005		Yes	No