UKALL R2 - Acute Lymphoblastic Leukaemia trial

Submission date 06/04/2000	Recruitment status No longer recruiting	
Registration date 06/04/2000	Overall study status Completed	[_] [X]
Last Edited 04/10/2007	Condition category Cancer	

Prospectively registered

-] Protocol
- Statistical analysis plan
- K] Results
-] Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Dr PJ Darbyshire

Contact details

The Children's Hospital Ladywood Middleway Birmingham United Kingdom B16 8ET

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

 They are multiply relapsed patients
They have a prior history of toxicity or organ damage such that completion of the protocol is felt unlikely at the outset
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 Results article Details Date created Results 01/07/2005

Date added

Peer reviewed?

Patient-facing?

Yes