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Medical Research Council Acute Lymphoblastic Leukaemia Trial in Children UKALL R1

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 20/06/2012	**Condition category** 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

Protocol serial number
MRC UKALL R1

Study information

Scientific Title

Study objectives
Not provided at time of registration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local research ethics committee approval.

Study design
Randomised controlled trial.

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
INDUCTION THERAPY:
All patients receive induction chemotherapy with allopurinol, dexamethasone, vincristine, aspariganase and etoposide plus intrathecal methotrexate, cystarabine and hydrocortisone.

CONSOLIDATION THERAPY:
Patients receive consolidation therapy with etoposide, cytarabine and intrathecal methotrexate followed by dexamethosone, asparaginase, epirubicin and vincristine then thioguanine, cytarabine, cyclophosphamide and intrathecal methotrexate.

CONTINUATION THERAPY:
Following consolidation patients are treated according to their initial randomisation:
1. Regimen A: A marrow-ablative regimen of cyclophosphamide and allopurin plus total body irradiation followed by autologous Bone Marrow Transplant (BMT) or allogenic BMT.
2. Regimen B: High dose methotrexate followed by continuation treatment with prednisolone, vincristine, mercaptopurine, methotrexate, thioguanine, etoposide, cytarabine, cyclophosphamide and intrathecal methotrexate. The duration of therapy is eight cycles each taking 9 weeks.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Not provided at time of registration.

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

Completion date

30/04/1995

Eligibility

Key inclusion criteria
1. Children under the age of 25 years at original diagnosis with first relapse of ALL at any site from previous UKALL trials or pilot studies
2. Multiple relapsed patients are excluded
3. Patients with prior history of toxicity or organ damage such that completion of the protocol is felt unlikely at the outset are to be excluded
4. Patients with Central Nervous System (CNS) relapse must have had prior radiotherapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/02/1991

Date of final enrolment
30/04/1995

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
Government

Funder Name
Medical Research Council (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

Funder Name
European Organisation for Research and Treatment of Cancer (EORTC)

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	01/08/2000		Yes	No