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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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Not provided at time of registration.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/02/1991

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
256 patients were recruited.

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
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

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

Funder(s)

Funder type
Government

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

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

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	01/08/2000		Yes	No