

Medical Research Council Acute Lymphoblastic Leukaemia Trial in Children UKALL R1

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/06/2012	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

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, asparaginase and etoposide plus intrathecal methotrexate, cytarabine and hydrocortisone.

CONSOLIDATION THERAPY:

Patients receive consolidation therapy with etoposide, cytarabine and intrathecal methotrexate followed by dexamethasone, 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 allogeneic 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)

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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