

MRC ALL 97 - UK national lymphoblastic leukaemia (ALL) trial

Submission date 25/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/10/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/08/2009	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
Dr C Mitchell

Contact details
Consultant Paediatric Oncologist
John Radcliffe Hospital
Headington
Oxford
United Kingdom
OX3 9DV

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00003437

Secondary identifying numbers
G8223452

Study information

Scientific Title

Acronym

MRC ALL 97

Study objectives

To compare, in a randomised fashion the effect on remission rate, event-free survival and overall survival of i) receiving, both during induction and continuing treatment, either oral prednisolone or dexamethasone, ii) receiving, where appropriate and throughout treatment (apart from intensive blocks) either oral 6-mercaptopurine or 6-thioguanine. To assess the effect on event-free survival for all patients of a schedule concentrating on tight control of maintenance therapy. To collect data on i) thiopurine metabolites on serial blood samples to assess the adequacy of therapy and to compare the pharmacokinetics of 6-MP and 6-TG, and ii) the presence or absence of minimal residual disease in serial bone marrow samples to assess its clinical importance. Also, two randomisations will be carried forward from the previous trial (UKALL XI) until sufficient numbers have accrued to answer the questions to which they relate, so subsidiary objectives are i) to continue to study, in a prospective randomised manner, the effect of either two or three blocks of intensive therapy, and ii) to continue to study the effect of high-dose methotrexate or cranial irradiation for patients with presenting white counts in excess of $50 \times 10^9/l$.

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)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Leukaemia

Interventions

Oral prednisolone/dexamethasone/Oral 6-mercaptopurine/6-thioguanine

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Disease-free survival
2. CNS disease eradication
3. Relapse rates

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1997

Completion date

30/06/2002

Eligibility**Key inclusion criteria**

Open to all children with ALL except those in 'Exclusions'

Participant type(s)

Patient

Age group

Child

Lower age limit

1 Years

Upper age limit

18 Years

Sex

Not Specified

Target number of participants

1800

Key exclusion criteria

1. Patients under 1 year or over 18 years,
2. B-ALL, Ph positivity, near haploidy in blasts or rearrangements involving the MLL gene on 11q23 and

3. High risk by Oxford Hazard Score (based on a function of age, gender and diagnostic leucocyte count)

Date of first enrolment

01/01/1997

Date of final enrolment

30/06/2002

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Consultant Paediatric Oncologist

Oxford

United Kingdom

OX3 9DV

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

Medical Research Council (MRC) (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

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	01/04/2005		Yes	No