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

Submission date 25/10/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/10/2000	**Overall study status** Completed	
Last Edited 13/08/2009	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 x 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
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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