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United Kingdom childhood Acute Lymphoblastic Leukaemia Randomised Trial 2003

Submission date 15/08/2003	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/08/2003	**Overall study status** Completed	
Last Edited 02/08/2019	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-chemotherapy-for-children-and-young-people-with-acute-lymphoblastic-leukaemia

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00222612

Protocol serial number
G0300130; 0301

Study information

Scientific Title
A randomised trial to evaluate whether treatment can be reduced without compromising effficacy in a low risk group of patients defined by a molecular minimal residual disease (MRD) technique; and to evaluate whether further post-remission intensification can improve outcome for a MRD-defined high risk group

Acronym
MRC UKALL 2003

Study objectives
Optimise treatment of childhood acute lymphoblastic leukaemia (ALL) by stratification according to on-treatment monitoring of minimal residual disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. MREC approval: Scotland A Research Ethics Committee, 25/02/2003, ref: 02/10/052
2. Medicines and Healthcare products Regulatory Agency (MHRA) approved of DDX Asparaginase Medac on 16/08/2002, DDX Oncaspar on 16/08/2002 and CTA Mercaptopurine 10 mg tablets on 16/06/2004 (ref: 18739/0205/001-0009)

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Interventions
MRD high risk group randomised to standard versus intensified therapy
MRD low risk group randomised to standard versus reduced therapy

Total duration of treatment was 2 years for girls, 3 years for boys and a 5 year follow-up for all arms.

Intervention Type
Other

Phase
Phase III

Primary outcome(s)

Event-free survival, measured at 5 years

Key secondary outcome(s)
1. Survival, measured at 5 years
2. Quality of life, measured at week 1, week 4, start of maintenance treatment, 18 months, end of treatment
3. Complete response (CR) rate measured at 4 weeks

Completion date
30/06/2011

Eligibility

Key inclusion criteria
Children aged 1 - 18 years with ALL

As of 12/02/2010, young adults up to their 25th birthday are also eligible for this trial.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 Years

Upper age limit
18 Years

Sex
All

Key exclusion criteria
1. Mature B ALL
2. Infant ALL (aged less than 1 year)
3. Philadelphia positive ALL

Date of first enrolment
01/10/2003

Date of final enrolment
30/06/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Sheffield Children's Hospital
Sheffield
United Kingdom
S10 2TH

Sponsor information

Organisation
University of Sheffield (UK)

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (MRC) (UK) (ref: G0300130)

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

Leukaemia Research Fund (UK) (ref: 0301)

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	01/03/2013		Yes	No
Results article	results	01/07/2014		Yes	No
Results article	results	14/08/2014		Yes	No
Results article	results	01/07/2018	02/08/2019	Yes	No
Other publications	retrospective observational analysis	05/10/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes