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# United Kingdom childhood Acute Lymphoblastic Leukaemia Randomised Trial 2003

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

### Study design
Randomised controlled trial

### Primary study design
Interventional

### 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 |