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# UKALL XI (92) - Acute lymphoblastic leukaemia trial

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 25/10/2000 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 25/10/2000 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 01/09/2022 | Cancer | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
G8223452

## Study information

**Scientific Title**
UKALL XI (92) - Acute lymphoblastic leukaemia trial

**Acronym**

UKALL XI (92)

### Study objectives
To test if CNS disease eradication can be successfully achieved without cranial radiotherapy by using CNS directed chemotherapy, to determine whether the use of high-dose intravenous MTX as part of the CNS therapy will reduce the incidence of systematic relapse, to assess whether a third intensification block of chemotherapy effects disease free survival, to compare by psychometric testing the long term learning and neuropsychological effects of the different CNS treatments.

Please note that the target number of participants was added as of 18/07/2007.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration.

### Primary study design
Interventional

### Study design
Randomised controlled trial

### Study type(s)
Treatment

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

### Interventions
Central Nervous System (CNS) directed chemotherapy/control

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome(s)
Disease-free survival, CNS disease eradication, relapse rates, psychometric test results.

### Key secondary outcome(s)
Not provided at time of registration

### Completion date
31/12/1997

## Eligibility

### Key inclusion criteria
They are children including those with Down's syndrome or leukaemia associated chromosome translocations over 1 year and under 15 years with newly diagnosed ALL of any immunologic subtype except B-ALL

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
1 Years

### Upper age limit
15 Years

### Sex
All

### Key exclusion criteria
Children with B-ALL and those under 1 year

### Date of first enrolment
01/01/1990

### Date of final enrolment
31/12/1997

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**The Children's Hospital**
Birmingham
United Kingdom
B16 8ET

## Sponsor information

**Organisation**
Medical Research Council (MRC) (UK)

# Funder(s)

**Funder type**
Research council

**Funder Name**
Medical Research Council (UK)

**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

# Results and Publications

**Individual participant data (IPD) sharing plan**
Not provided at time of registration

**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 | | 01/02/2002 | | Yes | No |
| Results article | | 01/01/2004 | | Yes | No |
| Results article | | 13/10/2011 | 01/09/2022 | Yes | No |
| Protocol article | | 01/04/2001 | | Yes | No |