

# United Kingdom Trial for children and young adults with Acute lymphoblastic Leukaemia and Lymphoma 2011

<b>Submission date</b> 08/12/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 08/12/2011	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/05/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-treatment-children-young-people-acute-lymphoblastic-leukaemia-lymphoma-ukall-2011>

## Study website

<https://bloodwise.org.uk/research/clinical-trials/ukall-2011>

## Contact information

### Type(s)

Scientific

### Contact name

Ms Kate Chew

### Contact details

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## Additional identifiers

EudraCT/CTIS number

2010-020924-22

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

11319

## **Study information**

### **Scientific Title**

United Kingdom national randomised trial for children and young adults with Acute lymphoblastic Leukaemia and Lymphoma 2011

### **Acronym**

UKALL 2011

### **Study objectives**

The UKALL 2011 trial seeks to further refine treatment for children and young adults suffering from acute lymphoblastic leukaemia, which is the commonest cancer of childhood, and the rarer condition, lymphoblastic lymphoma.

The aim is to improve survival whilst reducing the burden of therapy for patients, carers and the NHS. Although over 80% of patients with these diagnoses can be cured, there are considerable short term and long term side effects associated with the treatment.

The UKALL 2011 trial will build on the current best available treatment and will assess whether changes in the way some of the standard anti-leukaemia drugs are given can reduce the side effects associated with treatment. The changes to be tested include:

1. Modification of the scheduling of the steroid drug dexamethasone given in the first 4 weeks of treatment
2. Modification of the type of treatment given to prevent the disease returning in the central nervous system (CNS)
3. Modification of the type of 'maintenance treatment' used at the end of treatment

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

North Thames REC, 06/12/2011, ref: 11/LO/1487

### **Study design**

Randomized interventional treatment trial

### **Primary study design**

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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

Paediatric Oncology; Disease: Lymphoma (Hodgkin's), Leukaemia (acute lymphoblastic)

## Interventions

The trial will open in 27 UK principal treatment centres for children and young adults. Eligible patients will have acute lymphoblastic leukaemia or lymphoblastic lymphoma and will be aged between 1 and 25 years. Approximately 2640 patients will be recruited over 6 years.

The trial contains two randomisations and will investigate the following:

### 1. Randomisation 1 (R1) - dexamethasone randomisation:

In induction, the effect on serious treatment-related toxicity of receiving either a dexamethasone schedule of 10mg/m<sup>2</sup> per day for a total of 14 days, or the current standard UK schedule of 6mg/m<sup>2</sup> per day for 28 days.

### 2. Randomisation 2 (R2) - methotrexate and pulses randomisation:

In interim maintenance, the effect on CNS relapse risk and quality of life of receiving either high dose methotrexate without prolonged intrathecal therapy or the current standard UK CNS-directed ALL therapy with protracted intrathecal therapy.

### 3. Control:

In maintenance therapy, the effect in patients on bone marrow relapse risk and quality of life of receiving monthly pulses of vincristine and dexamethasone

## Intervention Type

Drug

## Phase

Phase III

## Drug/device/biological/vaccine name(s)

Dexamethasone, methotrexate, vincristine

## Primary outcome measure

### 1. Dexamethasone Randomisation (1st Randomisation, R1)

Induction steroid-induced morbidity and mortality defined as all serious adverse events and grade 3 or 4 adverse events related to induction and categorised as steroid related or steroid contributory

## 2. Methotrexate Randomisation (2nd Randomisation, R2)

Central nervous system (CNS) relapse, defined as any relapse with CNS involvement, including combined

## 3. Pulses Randomisation (2nd Randomisation, R2)

Bone marrow relapse, defined as any relapse with bone marrow involvement, including combined, Quality of Life measured by PedsQL

Added 08/03/2018:

Any event defined as relapse, secondary tumour or death from any cause is also a primary outcome measure for each randomised comparison and the trial overall.

### **Secondary outcome measures**

#### 1. Dexamethasone Randomisation (R1)

Rate of remission, event free and overall survival

#### 2. Methotrexate Randomisation (R2)

Event free and overall survival, Quality of Life measured by PedsQL, treatment related mortality and morbidity

#### 3. Pulses Randomisation (R2)

Event free and overall survival, treatment related mortality and morbidity, local relapse (LBL)

Added 08/03/2018:

#### 4. Overall trial population

Event free and overall survival, relapse rate, treatment related mortality and morbidity compared to the results from the UKALL 2003 trial

### **Overall study start date**

01/01/2012

### **Completion date**

31/12/2027

## **Eligibility**

### **Key inclusion criteria**

1. Aged 1 (first birthday) to 24 years 364 days (at time of diagnosis)
2. First diagnosis of acute lymphoblastic leukaemia or lymphoblastic lymphoma (T-NHL or SmIG negative precursor B-NHL) diagnoses using standard criteria
3. Male and female participants

### **Participant type(s)**

Patient

### **Age group**

Mixed

### **Lower age limit**

1 Years

### **Upper age limit**

24 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 2640; UK Sample Size: 2640

**Total final enrolment**

2822

**Key exclusion criteria**

1. Infants less than a year old at diagnosis
2. Patients diagnosed with B-ALL (Burkitt-like, t(8;14), L3 morphology, SMIg positive)
3. Patients diagnosed with Philadelphia-positive ALL (t(9;22) or BCR/ABL positive)
4. Patients in whom written informed consent has not been obtained from parents and/or patients prior to randomisation
5. Patients who have received previous treatment for ALL or lymphoblastic lymphoma (LBL) except those patients who have received dexamethasone treatment for no more than 7 days (due to clinical urgency) immediately prior to randomisation

**Date of first enrolment**

01/01/2012

**Date of final enrolment**

31/12/2018

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

Birmingham Clinical Trials Unit

Birmingham

United Kingdom

B15 2TT

**Sponsor information****Organisation**

University of Birmingham (UK)

**Sponsor details**

Cancer Research UK  
Clinical Trials Unit  
Institute for Cancer Studies  
Edgbaston  
Birmingham  
England  
United Kingdom  
B15 2TT

**Sponsor type**

University/education

**Website**

<http://www.birmingham.ac.uk/>

**ROR**

<https://ror.org/03angcq70>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Bloodwise

**Alternative Name(s)****Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal.

**Intention to publish date**

31/12/2028

## Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version 3.0	01/10/2013	05/05/2023	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Results article</a>		20/05/2025	19/05/2025	Yes	No