ISRCTN64515327 https://doi.org/10.1186/ISRCTN64515327

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

Submission date 08/12/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/12/2011	**Overall study status** Ongoing	
Last Edited 19/05/2025	**Condition category** Cancer	

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

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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 efefcts 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/m2 per day for a total of 14 days, or the current standard UK schedule of 6mg/m2 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 line 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
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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?
Protocol file	version 3.0	01/10/2013	05/05/2023	No	No
HRA research summary			28/06/2023	No	No
Results article		20/05/2025	19/05/2025	Yes	No