

UKALL XI (92) - Acute lymphoblastic leukaemia trial

Submission date 25/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/10/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/09/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

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.

Study design

Randomised controlled trial

Primary study design

Intentional

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