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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Central Nervous System (CNS) directed chemotherapy/control

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Disease-free survival, CNS disease eradication, relapse rates, psychometric test results.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1990

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

Age group
Child

Lower age limit
1 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
2,090 children were recruited

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
England

United Kingdom

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

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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Sponsor type
Research council

Website
http://www.mrc.ac.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, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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