UKALL XI (92) - Acute lymphoblastic leukaemia trial

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr F Hill

Contact details

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none@example.com

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 London United Kingdom W1B 1AL +44 (0)20 7636 5422 clinical.trial@headoffice.mrc.ac.uk

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