

Treatment of mature B-cell lymphoma /leukaemia

Submission date 01/07/2001	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/07/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/01/2019	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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00162656

Secondary identifying numbers
NHL9603

Study information

Scientific Title

Randomized international FAB/LMB96 trial for intermediate risk B-cell non-Hodgkin lymphoma in children and adolescents: it is possible to reduce treatment for the early responding patients.

Study objectives

Not provided at time of registration

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

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

Health condition(s) or problem(s) studied

Lymphoma (non-Hodgkins), leukaemia (acute)

Interventions

1. Arm A: A single course of cyclophosphamide, vincristine, prednisolone (COP) followed by two courses of chemotherapy with cyclophosphamide, vincristine, prednisolone, adriamycin, hydrocortisone and methotrexate (COPADM). Patients then receive two courses of etoposide alternating with a single dose of methotrexate. This is followed by four courses of maintenance therapy.
2. Arm B: A single course of COP followed by two courses of COPADM. Patients then receive two courses of reduced dose etoposide alternating with a single dose of methotrexate. This is followed by a single course of maintenance therapy.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cyclophosphamide, vincristine, prednisolone (COP) Cyclophosphamide, vincristine, prednisolone, adriamycin, hydrocortisone and methotrexate (COPADM).

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1997

Completion date

15/06/2001

Eligibility**Key inclusion criteria**

1. B-large cell, small non-cleaved non-Hodgkin's disease or B-cell leukaemia
2. Stages I-IV
3. Aged over 6 months and under 18 years
4. No previous chemotherapy. Emergency radiotherapy or immunotherapy is permitted
5. No congenital immunodeficiency
6. No prior organ transplantation
7. No previous malignancy of any type
8. No medical contraindications to protocol treatments
9. Patients available for a minimal follow-up of 36 months

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Months

Upper age limit

18 Years

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1997

Date of final enrolment

15/06/2001

Locations

Countries of recruitment

England

France

United Kingdom

United States of America

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Cancer Research UK (CRUK) (UK)

Sponsor details

PO Box 123

Lincoln's Inn Fields

London

United Kingdom

WC2A 3PX

+44 (0)207 317 5186

kate.law@cancer.org.uk

Sponsor type

Charity

Website

<http://www.cancer.org.uk>

ROR

<https://ror.org/054225q67>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Funder Name

United Kingdom Children's Cancer Study Group (UKCCSG)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	results	01/04/2007	25/01/2019	Yes	No