ISRCTN17584197 https://doi.org/10.1186/ISRCTN17584197

Treatment of mature B-cell lymphoma /leukaemia

Submission date	Recruitment status	[_] Prospectively registered
01/07/2001	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/07/2001	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/01/2019	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00162656

Protocol serial number
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

Study type(s)
Treatment

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(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 months

Upper age limit
18 years

Sex

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
United Kingdom

England

France

United States of America

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (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, Cancer Research UK (CRUK), 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2007	25/01/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes