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
Dr - -

Contact details
UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

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