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Treatment of mature B-cell lymphoma /leukaemia

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 25/01/2019	**Condition category** 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
NHL9602

Study information

Scientific Title
Treatment of mature B-cell lymphoma/leukaemia

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Leukaemia (acute), lymphoma (non-Hodgkin's)

Interventions
Patients are randomised to one of four treatment arms:
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) followed by cytarabine, etoposide and a third course of COPADM
2. Arm 2: A single course of COP followed by two courses of COPADM then cytarabine followed by etoposide
3. Arm C: A single course of COP followed by two courses of modified COPADM in which the dose of cyclophosphamide has been halved. Patients then receive cytarabine followed by etoposide and a third course of COPADM
4. Arm D: A single course of COP followed by two courses of modified COPADM in which the dose of cyclophosphamide has been halved. Patients then receive cytarabine followed by etoposide

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cyclophosphamide, vincristine, prednisolone, adriamycin, hydrocortisone, methotrexate, cytarabine, etoposide

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
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1998

Date of final enrolment
15/06/2001

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MRC Clinical Trials Unit
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