# Treatment of mature B-cell lymphoma /leukaemia

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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

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

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### 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))

#### 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

#### Kev 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

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

Participant information sheet Participant information sheet 11/11/2025 No Yes