Randomised comparison of cyclical anthracylinebased chemotherapy [PA(B1)OE] with alternating chemotherapy [Ch1VPP/PABLOE] in advanced Hodgkin's disease

Submission date	Recruitment status No longer recruiting	Prospectively registered	
01/07/2001		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
01/07/2001	Completed	[X] Results	
Last Edited	Condition category	[] Individual participant data	
01/02/2012	Cancer		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

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Additional identifiers

Protocol serial number HO3001

Study information

Scientific Title

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 (Hodgkin's)

Interventions

FIRST RANDOMISATION: Patients are randomised to one of two chemotherapy regimens:

- 1. PA(B1)OE Regimen: Multi-drug chemotherapy with adriamycin, vincristine, prednisolone, etoposide and bleomycin (PA(B1)OE) repeated every 21 days for six to eight courses. Bleomycin is given for the first four course only.
- 2. Ch1VPP/PABLOE Regimen: Multi-drug chemotherapy with chlorambucil, procarbazine, prednisolone and vinblastine(CH1VPP) alternating with PA(B1)OE. The total cycle Ch1VPP/PA (B1)OE takes 7 weeks. A minimum of six, three each of Ch1VPP and PA(B1)OE, and a maximum of eight courses of chemotherapy to be given.

SECOND RANDOMISATION: Patients in complete remission following chemotherapy whose original presentation was with bulky (>5 cm) nodal disease are eligible for the second randomisation. Patients are randomised to one of two groups:

- 1. Group A: Radiotherapy 35-40 Gy given over 4 weeks.
- 2. Group B: No radiotherapy.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cancer drugs

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date

01/04/1996

Eligibility

Key inclusion criteria

- 1. Previously untreated and properly stage patients with Hodgkin's disease for whom chemotherapy is indicated, ie stage I and IIA (poor prognosis), IB, IIB, III and IV
- 2. Patients must be free from any irreversible medical condition that would drastically limit their life span or prohibit use of combination chemotherapy
- 3. Aged 15 to 69 years inclusive

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1990

Date of final enrolment

01/04/1996

Locations

Countries of recruitment

United Kingdom

England

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

British National Lymphoma Investigation (BNLI)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type

Details

Results article	Results	18/05/2001	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025 No	Yes