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

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 01/02/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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 (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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1990

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

Age group
Adult

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

01/01/1990

Date of final enrolment
01/04/1996

Locations

Countries of recruitment
England

United Kingdom

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
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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
British National Lymphoma Investigation (BNLI)

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	18/05/2001		Yes	No