A randomised trial of therapy in advanced Hodgkin's disease

Submission date	Recruitment status No longer recruiting	Prospectively registered	
01/07/2001		Protocol	
Registration date	Overall study status Completed	Statistical analysis plan	
01/07/2001		[X] Results	
Last Edited	Condition category	Individual participant data	
26/10/2022	Cancer		

Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-chemotherapy-hodgkins-lymphoma

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)

NCT00003421

Protocol serial number

LY09

Study information

Scientific Title

A randomised trial of therapy in advanced Hodgkin's disease

Study objectives

To perform an open-label, randomized, controlled trial comparing treatment with doxorubicin, bleomycin, vinblastine, and dacarbazine (ABVD) with two multidrug regimens (MDRs) for advanced Hodgkin's lymphoma (HL).

More details can be found at: http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=97

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Open label randomised active controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hodgkin's lymphoma

Interventions

Patients with advanced HL (stage III to IV, or earlier stage with systemic symptoms or bulky disease) were randomly assigned between ABVD and MDR specified before randomization as alternating chlorambucil, vinblastine, procarbazine, and prednisolone (ChlVPP) with prednisolone, doxorubicin, bleomycin, vincristine, and etoposide (PABIOE), or hybrid ChlVPP /etoposide, vincristine, and doxorubicin (EVA). Radiotherapy was planned for incomplete response or initial bulk disease.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Doxorubicin, bleomycin, vinblastine, dacarbazine, chlorambucil, vinblastine, procarbazine, prednisolone, vincristine, etoposide

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date

01/01/2002

Eligibility

Key inclusion criteria

- 1. Histologically proven Hodgkin's Disease requiring systemic therapy (this may also include patients with Clinical Stage IA or IIA in the presence of adverse factors, eg bulky disease or more than three sites of involvement)
- 2. Patient fit and able to receive chemotherapy
- 3. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

807

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1998

Date of final enrolment

01/01/2002

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 (CRUK) (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

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created Date added	Peer reviewed?	Patient-facing?
Results article	results	20/12/2005	Yes	No
Results article	results	10/07/2010	Yes	No
	Participant information sheet			

Participant information sheet
Plain English results

11/11/2025 No 26/10/2022 No Yes Yes