ISRCTN97144519 https://doi.org/10.1186/ISRCTN97144519

A randomised trial of therapy 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 26/10/2022	**Condition category** 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
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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

Primary study design
Interventional

Study design
Open label randomised active controlled trial

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
Plain English results			26/10/2022	No	Yes