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 01/07/2001	Overall study status Completed	Statistical analysis plan		
		[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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00003421

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

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

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1998

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

Age group

Adult

Sex

Both

Target number of participants

807

Total final enrolment

807

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1998

Date of final enrolment

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 +44 (0)207 317 5186 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 (CRUK) (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

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

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	20/12/2005		Yes	No
Results article	results	10/07/2010		Yes	No
Plain English results			26/10/2022	No	Yes