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

# A randomised trial of therapy in advanced Hodgkin's disease

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

01/01/2002

# 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 |