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A Phase III Study of Radiotherapy or ABVD Plus Radiotherapy Versus ABVD Alone in the Treatment of Early Stage Hodgkin's Disease

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 17/05/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00002561

Protocol serial number
HD305

Study information

Scientific Title
A Phase III Study of Radiotherapy or ABVD Plus Radiotherapy Versus ABVD Alone in the Treatment of Early Stage Hodgkin's Disease

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

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Lymphoma (Hodgkin's)

Interventions
Patients are divided into two cohorts based on risk factors and randomised to receive either standard treatment (radiation or combined modality therapy according to cohort assignment) or experimental treatment (ABVD):

1. STANDARD ARM:
A. Cohort 1: Radiotherapy only.
B. Cohort 2: Chemotherapy, adriamycin, bleomycin, vinblastine and decarbazine (ABVD) given intravenously on days 1 and 15 of a 28 day cycle. Two cycles of ABVD to be followed by radiotherapy.

2. EXPERIMENTAL ARM:
Chemotherapy, ABVD given intravenously on days 1 and 15 of a 28 day cycle. Patients initially receive two cycles of ABVD followed by restaging. Patients in complete remission receive a further two cycles of ABVD, and those patients assessed as achieving a partial remission and not demonstrating progressive disease receive a further four cycles of ABVD.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Not provided at time of registration.

Key secondary outcome(s))
Not provided at time of registration.

Completion date
22/07/1999

Eligibility

Key inclusion criteria
1. Histologically proven Hodgkin's disease
2. Ann Arbor stage I-IIa disease
3. Age between 16 and 70 years
4. No prior chemotherapy or radiotherapy
5. No prior or concurrent malignancies, except treated basal cell carcinoma
6. No cardiac disease
7. No stage Ia disease which is treatable with involved field only irradiation
8. No interabdominal disease
9. No B symptoms
10. No known Human Immunodeficiency Virus (HIV) infection

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Total final enrolment
405

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
22/07/1994

Date of final enrolment
22/07/1999

Locations

Countries of recruitment
United Kingdom

England

Canada

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
National Cancer Institute of Canada Clinical Trials Group (NCIC CTG)

Funder(s)

Funder type
Government

Funder Name
National Cancer Institute of Canada Clinical Trials Group

Results and Publications

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	02/02/2012	17/05/2019	Yes	No