ISRCTN64141244 https://doi.org/10.1186/ISRCTN64141244

Protocol for a Randomised Phase II Study of the Stanford V regimen compared with ABVD for the treatment of Advanced 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 18/10/2018	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-comparing-stanford-v-chemotherapy-with-abvd-chemotherapy-for-advanced-hodgkins-lymphoma

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
STANFORD V

Study information

Scientific Title

Protocol for a Randomised Phase II Study of the Stanford V regimen compared with ABVD for the treatment of Advanced Hodgkin's Disease

Study objectives
To compare the Stanford V regimen with Adriamycin, Bleomycin, Vinblastine, Dacarbazine (ABVD) for the treatment of Advanced Hodgkin's Disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This trial is currently awaiting approval for an amendment, and sites will be able to recruit once this has been granted.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Interventions
STANFORD V regimen: Chemotherapy with mustine, doxorubicin, vinblastine, prednisolone, vincristine, bleomycin and etoposide

ABVD Regimen: Chemotherapy with doxorubicin, bleomycin, vinblastine and dacarbazine

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Mustine, doxorubicin, vinblastine, prednisolone, vincristine, bleomycin, etoposide and dacarbazine.

Primary outcome(s)
Not provided at time of registration

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

Completion date
30/06/2008

Eligibility

Key inclusion criteria
1. Histologically confirmed Hodgkin's disease
2. Clinical stage IIB, IIIA, IIIB or IV
3. Aged 18 - 60 years
4. No previous history of malignancy, except for basal cell or squamous cell carcinoma of the skin
5. Normal values for Full Blood Count (FBC), hepatic and renal function, unless directly attributable to involvement by Hodgkin's disease
6. Written informed consent
7. All patients must be assessed by the treating haematologist/medical oncologist and radiation oncologist TOGETHER prior to study entry. This is an absolute requirement for the study eligibility

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Key exclusion criteria
1. Previous therapy for Hodgkins disease
2. Clinical evidence of infection with the Human Immunodeficiency Virus (HIV)
3. Pre-existing cardiac or pulmonary disease

Date of first enrolment
01/01/2001

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Lymphoma Trials Office
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
British National Lymphoma Investigation (BNLI) (UK)

Funder(s)

Funder type
Research organisation

Funder Name
British National Lymphoma Investigation (BNLI) (UK)

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	10/11/2009		Yes	No
Other publications	questionnaire-based audit	01/10/2007		Yes	No
Plain English results				No	Yes