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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

Registration date
19/08/2002

Overall study status
Completed

Last Edited
18/10/2018

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

Contact name
Mr Paul Mouncey

Contact details
Lymphoma Trials Office
222 Euston Road
London
United Kingdom
NW1 2DA
+44 (0) 20 7679 8038
pm@ctc.ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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.

Study design
Randomised 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
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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2001

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
700

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
England

United Kingdom

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

Sponsor information

Organisation
British National Lymphoma Investigation (BNLI) (UK)

Sponsor details
CRC and UCL Cancer Trials Centre
222 Euston Road
London
United Kingdom
NW1 2DA
+44 (0)20 7679 8060
bnli@ctc.ucl.ac.uk

Sponsor type
Charity

Website
http://www.bnli.ucl.ac.uk

Funder(s)

Funder type
Research organisation

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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