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A phase II study of vinblastine, endoxana (cyclophosphamide), procarbazine, prednisolone, etoposide, mitoxantrone and bleomycin in patients with Hodgkin's lymphoma aged over 60 years

Submission date
04/08/2006

Recruitment status
No longer recruiting

Registration date
18/08/2006

Overall study status
Completed

Last Edited
21/02/2019

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-looking-at-vepemb-chemotherapy-for-patients-over-60-years-old-with-hodgkins-lymphoma

Study website
http://www.shieldstudy.co.uk

Contact information

Type(s)
Scientific

Contact name
Prof Stephen John Proctor

Contact details
Academic Haematology
Leech Building
Medical School
University of Newcastle upon Tyne
Newcastle upon Tyne
United Kingdom
NE2 4HH
+44 (0) 191 222 7791
s.j.proctor@ncl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00079105

Secondary identifying numbers
Version 3: 20.1.2005

Study information

Scientific Title
A phase II study of vinblastine, endoxana (cyclophosphamide), procarbazine, prednisolone, etoposide, mitoxantrone and bleomycin in patients with Hodgkin's lymphoma aged over 60 years

Acronym
SHIELD Study

Study objectives
Progress in the treatment of Hodgkins Lymphoma (HL) in patients under 60 years has been substantial but in the over 60 years age group only small studies have been conducted and limited progress in outcome has been seen. It is necessary to create a starting point of uniform treatment for HL in the over 60 years age group, giving potentially curative treatment in a form that would be acceptable to individuals in this age group.

Nationally and internationally there is no existing co-ordinated study of HL in this age group and recent data indicates that outcome has not improved in the last 15 years. A number of older patients with HL fail to enter clinical trials as they are "not fit" for multiple drug chemotherapy. This study will aim to register all pathologically eligible patients in participating centres in order to provide a clearer overall clinical picture of this disease, whether or not they undergo protocol chemotherapy.

This study is of a phase II nature that aims to assess the efficacy, toxicity and applicability of the Vinblastine, Endoxana (cyclophosphamide), Procarbazine, Prednisolone, Etoposide, Mitoxantrone and Bleomycin (VEPEMB) chemotherapy schedule in this particular patient population, as a prelude to a subsequent randomised trial. The linking of this phase II study with total data collection aims to assess:
1. The proportions of patients who can enter a study of curative intent within this age group.
2. To assess complete response rate, event free survival and overall survival following this treatment schedule.

Please note that, as of 12/12/2008, the anticipated end date of this trial has been updated from 31/08/2007 to 31/08/2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Thames Valley Multi-Centre Research Ethics Committee, reference number: 03/12/062.

Study design
Phase II two-arm non-randomised clinical study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: http://www.shieldstudy.co.uk/publicdocs/VEPEMBV5.doc

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

Interventions
The patient either receives the VEPEMB treatment or is simply registered on the database and the alternative treatment which they receive is recorded. The patient's treatment is determined by their physicians who assess their 'fragility'. If they are too 'fragile' they will not be given the VEPEMB regimen.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Vinblastine, Endoxana (cyclophosphamide), Procarbazine, Prednisolone, Etoposide, Mitoxantrone and Bleomycin

Primary outcome measure
The primary endpoints will be progression-free survival, with clinical progression and death as the events. On suspicion of progression (e.g. new or enlarging masses, development of B symptoms) patients should be re-evaluated according to normal procedures to confirm relapse. Histological confirmation of relapse is recommended but not mandatory.

Survival time, including death from any cause, will also be investigated. For both endpoints, the event-free times will be dated from the date of histological diagnosis.

Secondary outcome measures

Analysis will be done to assess potential prognostic factors (Epstein-Barr Virus [EBV] status, "Fragility" assessment, Hasenclever index, soluble form of the CD30 molecule [sCD30]) which might be relevant in this age group.

Overall study start date
01/09/2004

Completion date
31/08/2009

Eligibility

Key inclusion criteria
1. Histologically confirmed classical Hodgkin's Lymphoma (HL)
2. No previous treatment for HL
3. Aged over 60
4. "Non fragile" patients, i.e. patients mental and physical status must be sufficient to withstand the treatment described
5. No concomitant neoplasia or known Human Immunodeficiency Virus (HIV) infection
6. Written informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Nodular Lymphocyte Predominance Hodgkin's Lymphoma (NLPHL)
2. Aged under 60
3. Patient previously treated for HL
4. Known HIV infection or concomitant neoplasia
5. "Fragile patient" or significant abnormality of another system (pulmonary, cardiac, renal, and hepatic) which is a contraindication to full dose chemotherapy
6. Unable to give informed consent

Date of first enrolment
01/09/2004

Date of final enrolment
31/08/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Haematology
Newcastle upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
Newcastle Hospitals NHS Trust (UK)

Sponsor details
Research & Development
Royal Victoria Infirmary
Newcastle upon Tyne
England
United Kingdom
NE2 4HH

Sponsor type
Hospital/treatment centre

Website
http://www.shieldstudy.co.uk

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
Marrow & Stem Cell Transplant 2000 (The Millennium Fund) (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
Results article	results	21/06/2012		Yes	No