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HD15 for advanced stage Hodgkin's disease: Quality assurance protocol for reduction of toxicity and the prognostic relevance of fluorodeoxyglucose-positron-emission tomography (FDG-PET) in the first-line treatment of advanced stage Hodgkin's disease

Submission date 11/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/10/2003	**Overall study status** Completed	
Last Edited 07/10/2014	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
HD15

Study objectives
Primary aim:
Reduction of toxicity, de-escalation of chemotherapy while maintaining high freedom from treatment failure (FFTF) and overall survival (OS) rates.

Secondary aims:
Assess the influence of erythropoietin on the quality of life and the effect of FDG-PET on prognosis.

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information sheet can be found at http://www.lymphome.de/en/Groups/GHSG/Protocols/HD15/Patient-Information.pdf

Health condition(s) or problem(s) studied

Hodgkin's disease

Interventions
In this trial three combinations of chemotherapy are compared in a randomised, controlled trial (open-label). In addition patients in every arm are randomly assigned to receive erythropoetin or placebo (double-blind). Restaging with PET is not allocated in a randomised fashion:

Arm A:
1. 8 x erythropoietin, cyclophosphamide, adriamycin, etoposide, vincristine, bleomycin, procarbazine (BEACOPP) (escalated)
2. Erythropoetin/placebo
3. 30 Gy involved field radiotherapy if partial remission after chemotherapy and PET is positive

Arm B:
1. 6 x BEACOPP (escalated)
2. Erythropoetin/placebo
3. 30 Gy involved field radiotherapy if partial remission after chemotherapy and PET is positive

Arm C:
1. 8 x BEACOPP-14
2. Erythropoetin/placebo
3. 30 Gy involved field radiotherapy if partial remission after chemotherapy and PET is positive

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Erythropoietin, cyclophosphamide, adriamycin, etoposide, vincristine, bleomycin, procarbazine (BEACOPP)

Primary outcome measure
Freedom from treatment failure (FFTF).

Secondary outcome measures
Impact of erythropoetin on quality of life and prognostic significance of FDG-PET.

Overall study start date
01/01/2003

Completion date
01/01/2008

Eligibility

Key inclusion criteria
Chemotherapy:
1. Histologically confirmed Hodgkin's disease

2. Stage IIB and massive mediastinal involvement (tumour one third or more of the maximum intrathoracic diameter) and/or extranodal involvement, stage III, and stage IV
3. No prior therapy for Hodgkin's disease
4. Age: 18 - 60 years
5. No major organ dysfunction
6. Life expectancy greater than 3 months
7. Written informed consent

PET:
1. Chemotherapy according to the HD15-protocol
2. Response to chemotherapy
3. Partial response with residual disease of at least 2.5 cm maximum diameter

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
Chemotherapy:
1. Incomplete staging
2. Major organ dysfunction:
2.1. Chronic obstructive pulmonary disease (COPD) with respiratory insufficiency
2.2. Symptomatic coronary heart disease (CHD)
2.3. Cardiomyopathy or heart failure (ejection fraction less than 50%)
2.4. Severe hypertension
2.5. Non-treatable infections
2.6. White blood count less than 3000/mm^3 or platelets less than 100,000/mm^3 if not related to bone marrow involvement
2.7. Creatinine clearance less than 60 ml/min
2.8. Bilirubin greater than 2 mg/dl if not related to Hodgkin's disease
2.9. Glutamic oxaloacetic transaminase (GOT)/aspartate aminotransferase (AST) greater than 100 U/l if not related to Hodgkin's disease
2.10. Glutamic pyruvic transaminase (GPT)/alanine aminotransferase (ALT) greater than 100 U/l if not related to Hodgkin's disease
2.11. Human immunodeficiency virus (HIV)-infection
3. Composite lymphoma
4. Prior chemotherapy or radiotherapy
5. Any history of another malignancy in the last 5 years (except for cervical carcinoma in situ and fully resected melanoma TNMpT1)
6. Pregnancy or breastfeeding

7. World Health Organisation (WHO) performance status greater than 2
8. Long term use of corticosteroids (e.g. for arthritis) or antineoplastic substances (e.g. methotrexate)
9. Expected non-compliance
10. Current therapy for epilepsy
11. Intolerabilities against study drugs

PET:
1. Diabetes mellitus
2. Elevated blood glucose (greater than 130 mg/dl)
3. Massive bone involvement (endangering stability)

Date of first enrolment
01/01/2003

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Germany

Study participating centre
German Hodgkin's Lymphoma Study Group,
Cologne
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Sponsor information

Organisation
German Hodgkin's Lymphoma Study Group (Germany)

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Sponsor type
Research organisation

Funder(s)

Funder type
Charity

Funder Name
Deutsche Krebshilfe (Germany)

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?
Results article	results	15/11/2008		Yes	No
Results article	results	12/05/2012		Yes	No
Results article	results	10/06/2014		Yes	No