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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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/mm³ or platelets less than 100,000/mm³ 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 Germany 50924

Sponsor information

Organisation

German Hodgkin's Lymphoma Study Group (Germany)

Sponsor details

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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