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HD13 for early stage Hodgkin's disease: quality assurance protocol for reduction of toxicity in the first-line treatment of early stage Hodgkin's Disease (HD)

Submission date 12/09/2003	**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 11/07/2018	**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
HD13 for early stage Hodgkin's disease: quality assurance protocol for reduction of toxicity in the first-line treatment of early stage Hodgkin's Disease (HD)

Acronym
HD13

Study objectives
Reduction of toxicity through deescalation of chemotherapy while maintaining high Freedom From Treatment Failure (FFTF) and Overall Survival rates.

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 material can be found at http://www.lymphome.de/en/Groups/GHSG/Protocols/HD13/Patient-Information.pdf

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

Interventions
Arm A: 2 x Doxorubicin, Bleomycin, Vinblastine, Dacarbazine (ABVD) and 30 Gy Involved Field Radiotherapy (IF-RT)
Arm B: 2 x Doxorubicin, Bleomycin, Vinblastine (ABV) and 30 Gy IF-RT
Arm C: 2 x Doxorubicin, Vinblastine, Dacarbazine (AVD) and 30 Gy IF-RT
Arm D: 2 x Doxorubicin, Vinblastine (AV) and 30 Gy IF-RT

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Doxorubicin, Bleomycin, Vinblastine, Dacarbazine (ABVD)

Primary outcome measure
Freedom From Treatment Failure (FFTF) .

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2003

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Histologically confirmed Hodgkin's disease
2. Stages IA (not lympocyte predominant HD), IB, IIA, and IIB without the following risk factors:
2.1. Massive mediastinal involvement (tumour one third or more of the maximum intrathoracic diameter
2.2. Extranodal involvement
2.3. High Erythrocyte Sedimentation Rate (ESR) (greater than or equal to 50 mm; greater than or equal to 30 mm with B symptoms)
2.4. Three or more involved lymph node areas
3. No prior therapy for Hodgkin's disease
4. Aged 18 - 75 years
5. No major organ dysfunction
6. Life expectancy more than three months
7. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1250

Key exclusion criteria
1. Incomplete staging
2. Major organ dysfunction (Chronic Obstructive Pulmonary Disease [COPD] with respiratory insufficiency, symptomatic Coronary Heart Disease [CHD], cardiomyopathy or heart failure [ejection fraction less than 50%], severe hypertension, non-treatable infections, white blood count less than 3000/mm^3 or platelets less than 100,000/mm^3, creatinine clearance less than 60 ml/min, bilirubin more than 2 mg/dl, Glutamic-Oxaloacetic Transaminase [GOT]/aspartate aminotransferase [AST] more than 100 U/l, Glutamic-Pyruvic Transaminase [GPT]/alanine aminotransferase [ALT] more than 100 U/l, Human Immunodeficiency Virus [HIV]-infection)
3. Composite lymphoma
4. Prior chemotherapy or radiotherapy
5. Any history of another malignancy in the last five years (except for cervical carcinoma in situ and fully resected melanoma TNMpT1)
6. Pregnancy or breastfeeding
7. World Health Organization (WHO) performance status more than two
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
12. Inability to give truly informed consent

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)

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Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
Deutsche Krebshilfe

Alternative Name(s)
Stiftung Deutsche Krebshilfe, German Cancer Aid

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
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	11/04/2015		Yes	No
Results article	results	05/05/2016		Yes	No
Results article	results	01/09/2018		Yes	No