

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/10/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 11/07/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

Freedom From Treatment Failure (FFTF) .

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/01/2008

Eligibility

Key inclusion criteria

1. Histologically confirmed Hodgkin's disease
2. Stages IA (not lymphocyte 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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/mm³ or platelets less than 100,000/mm³, 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)

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes