ISRCTN63474366 https://doi.org/10.1186/ISRCTN63474366

# 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

**Registration date**
29/10/2003

**Overall study status**
Completed

**Last Edited**
11/07/2018

**Condition category**
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 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

### 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/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)

# 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 |