

HD14 for intermediate stage Hodgkin's disease: Quality assurance protocol to increase effectiveness in the first-line treatment of intermediate stage Hodgkin's disease

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/10/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/07/2018	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

Study information

Scientific Title
HD14 for intermediate stage Hodgkin's disease: Quality assurance protocol to increase effectiveness in the first-line treatment of intermediate stage Hodgkin's disease

Acronym

HD14

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Multicentre randomised open labeled active controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hodgkin's disease

Interventions

Primary objective: to increase effectiveness Arm A: 4 x ABVD + 30 Gy involved field radiotherapy

Arm B: 2 x BEACOPPescalated + 2 x ABVD + 30 Gy involved field radiotherapy

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Freedom From Treatment Failure [FFTF]

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/10/2004

Eligibility**Key inclusion criteria**

1. Histologically confirmed Hodgkin's disease
2. Stages IA, IB, and IIA with one or more of 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) (more than or equal to 50 mm; more than or equal to 30 mm in patients with B symptoms)
- 2.4. Three or more involved lymph node areas; stage IIB and high ESR (more than or equal to 30 mm) and/or three or more involved lymph node areas
3. No prior therapy for Hodgkin's disease
4. Age: 18 to 60 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. Pregnant or lactating women
7. World Health Organisation (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

01/10/2003

Date of final enrolment

01/10/2004

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	01/09/2018		Yes	No