ISRCTN04761296 https://doi.org/10.1186/ISRCTN04761296

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	[_] 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

Protocol serial number
N/A

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 labed 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/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 Immunodeficieny 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 lacating 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