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A randomised trial of BEAM plus peripheral blood stem cell transplantion (PBSCT) versus single agent high-dose therapy followed by BEAM plus PBSCT in patients with relapsed Hodgkin's disease

Submission date 11/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 29/10/2003	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 28/01/2019	**Condition category** Cancer	[_] 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

ClinicalTrials.gov (NCT)
NCT00025636

Study information

Scientific Title
A randomised trial of BEAM plus peripheral blood stem cell transplantion (PBSCT) versus single agent high-dose therapy followed by BEAM plus PBSCT in patients with relapsed Hodgkin's disease

Acronym
HD-R2

Study objectives
To compare efficacy and toxicity of a sequential HDCT and a standard HDCT in patients with histologically confirmed relapsed Hodgkins disease.

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
All patients will receive 2 cycles of Dexamethasone, Cytarabine, Cisplatin (DHAP) and Granulocyte Colony-Stimulating Factor (G-CSF). After the first (and/or second) course of DHAP, PBSC will be collected by apheresis. Response evaluation will then be performed and patients with CR/PR/stable disease will proceed as intended via randomisation:

Arm A: Carmustin, etoposide, cytarabine, melphalan (BEAM) and G-CSF followed by PBSCT
Arm B: High-dose cyclophosphamide, followed by high-dose methotrexate and vincristine, followed by high-dose etoposide, and BEAM and G-CSF followed by PBSCT

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)

Carmustin, etoposide, cytarabine, melphalan (BEAM), cyclophosphamide (CTX), methotrexate (MTX), vincristin, etoposide

Primary outcome(s)
Freedom From Treatment Failure (FFTF)

Key secondary outcome(s))
1. Complete Remission (CR), Complete Remission unconfirmed (CRu) rates 3 months after end of protocol
2. Relapse-Free Survival (RFS)
3. Overall Survival (OS)
4. Frequency of severe toxicities (World Health Organization [WHO] grade 3 or 4)
5. Secondary neoplasia

Completion date
01/07/2006

Eligibility

Key inclusion criteria
1. Histologically confirmed early or late first relapsed Hodgkin's disease or second relapsed Hodgkin's disease without prior high-dose chemotherapy
2. Age: 18 - 60 years
3. Eastern Cooperative Oncology Group (ECOG) less than or equal to 2, Karnofsky performance status equalling 70
4. Life expectancy greater than 3 months with treatment
5. Absolute Neutrophil Count (ANC) greater than 2.5 x 10^9/l and platelets greater than 100 x 10^9/l
6. 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. Active infection
2. Concurrent other malignancy other than adequately treated basal-cell carcinoma of the skin or cervical intra-epithelial neoplasia
3. Significant non-malignant disease:

3.1. Human Immunodeficiency Virus (HIV)-infection
3.2. Uncontrolled hypertension
3.3. Unstable angina
3.4. Heart failure (New York Heart Association [NYHA] II)
3.5. Chronic Obstructive Pulmonary Disease (COPD)
3.6. Poorly controlled diabetes mellitus
3.7. Cerebral disorder
3.8. Coronary angioplasty or myocardial infarction within the last 6 months
3.9. Uncontrolled atrial or ventricular cardiac arrythmias
4. Creatinine clearance less than 60 ml/min
5. Pregnancy or lactating women, non adequate contraception
6. Patients currently receiving investigational drugs
7. Inability to give truly informed consent

Date of first enrolment
01/07/2001

Date of final enrolment
01/07/2006

Locations

Countries of recruitment
Germany

Study participating centre
Department I of Internal Medicine
Cologne
Germany
50924

Sponsor information

Organisation
German Hodgkin's Lymphoma Study Group (Germany)

Funder(s)

Funder type
Research organisation

Funder Name

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	01/12/2010	28/01/2019	Yes	No
Protocol article	Protocol	01/08/2002		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes