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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

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Andreas Engert

**Contact details**
Department I of Internal Medicine
University of Cologne
Joseph-Stelzmann-Str. 9
Cologne
Germany
50924
+49 (0)221 478-5933 (3557/3558)
dhsg@biometrie.uni-koeln.de

## Additional identifiers

**ClinicalTrials.gov (NCT)**
NCT00025636

**Protocol serial number**
N/A

# 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**
European Group for Blood and Bone Marrow Transplantation (EORTC) Lymphoma Group

# 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 |