

A randomised trial of BEAM plus peripheral blood stem cell transplantation (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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 29/10/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/01/2019	Condition category Cancer	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00025636

Secondary identifying numbers

N/A

Study information

Scientific Title

A randomised trial of BEAM plus peripheral blood stem cell transplantation (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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Patient information material can be seen at <http://www.lymphome.de/Gruppen/GHSG/Protokolle/HD-R2/PatientInformation.pdf>

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 measure

Freedom From Treatment Failure (FFTF)

Secondary outcome measures

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

Overall study start date

01/07/2001

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 $2.5 \times 10^9/l$ and platelets greater than $100 \times 10^9/l$
6. Written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

220

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 arrhythmias
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

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Sponsor information

Organisation

German Hodgkin's Lymphoma Study Group (Germany)

Sponsor details

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Sponsor type

Research organisation

Website

<http://www.lymphome.de/en/Groups/GHSG/>

Funder(s)

Funder type

Research organisation

Funder Name

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

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Protocol article	Protocol	01/08/2002		Yes	No
Results article	results	01/12/2010	28/01/2019	Yes	No