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High dose therapy of relapsed or refractory aggressive non-Hodgkin lymphoma

Submission date
22/03/2012

Recruitment status
No longer recruiting

Registration date
30/03/2012

Overall study status
Completed

Last Edited
09/09/2016

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Non-Hodgkin lymphoma is an uncommon cancer that develops in the lymphatic system, which is a network of vessels and glands spread throughout the body. Patients whose disease does not respond to treatment (refractory) or whose disease returns (relapsed) have a dismal outcome. New treatments therefore need to be explored. High doses of chemotherapy drugs and radiotherapy are used to kill off the cancer cells but they also damage the bone marrow, including the stem cells. This means the body can't make any new blood cells. Before chemotherapy the patient’s stem cells are therefore frozen and stored, and after chemotherapy they are given back through a drip (autologous stem cell transplantation). It is also possible to have stem cells donated by the patient’s brother or sister (allogeneic stem cell transplantation). The aim of this study is to find out whether allogeneic stem cell transplantation is superior to autologous stem cell transplantation for patients with relapsed or refractory non-Hodgkin lymphoma.

Who can participate?
Patients age 18 - 65 with refractory or relapsed non-Hodgkin-lymphoma

What does the study involve?
Participants receive two cycles of immunochemotherapy (combined immunotherapy and chemotherapy). Patients who achieve a partial or complete remission (disappearance of signs and symptoms) after autologous transplantation receive a second autologous stem cell transplantation. Patients whose disease is either refractory or at early relapse receive allogeneic transplantation.

What are the possible benefits and risks of participating?
A possible benefit from this study is a higher probability to survive the disease. Potential risks include infectious complications and development of graft-versus-host disease (where the donated cells attack the body).

Where is the study run from?
Eastern German Study Group for Hematology and Oncology (OSHO)

When is the study starting and how long is it expected to run for?
August 2004 to December 2012

Who is funding the study?
Costs are covered by the participating centers with refunding from the German health insurance system

Who is the main contact?
Prof. Dr. Michael Koenigsmann
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Study website
http://www.lymphome.de/Gruppen/OSHO/Protokolle/71/index.jsp

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OSHO #71

Study information

Scientific Title
High dose therapy of relapsed or refractory aggressive non-Hodgkin lymphoma: a phase II study

Study objectives
Allogeneic stem cell transplantation is superior to autologous stem cell transplantation in this setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the University of Magdeburg, Magdeburg, Germany, 22/04/2004, ref: 46/04

Study design
Non-randomized phase II trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Refractory or relapsed non-Hodgkin lymphoma

Interventions
Two cycles of rituximab, dexamethasone, cytarabine, cisplatin (R-DHAP) regimen immunochemotherapy are performed including rituxan (anti-CD20 monoclonal antibody), dexamethasone, high dose cytarabin and cisplatin.

Treatment arm 1: Patients who received a partial or complete remission after autologous transplantation were subjected to a second autologous stem cell transplantation

Tretament arm 2: Patients in whom non-Hodgkin lymphoma (NHL) is either refractory or at early relapse, i.e. occurs within 12 months from first CR. They will receive an allo-graft if an allo-graft is available.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Rituximab, dexamethasone, cytarabine, cisplatin (R-DHAP)

Primary outcome measure

1. Toxicity of the regimen
2. Overall survival
3. Disease free survival

Secondary outcome measures
1. Development of graft-versus-host-disease (GVHD)
2. Minimal residual disease (MRD)

Overall study start date
01/08/2004

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Refractory or relapsed aggressive Non-Hodgkin lymphoma
2. Age 18 - 65 years
3. Performance-Status (Karnofsky more than 60 %)
4. Absolute neutrophil count (ANC) >1.5/µl
5. Platelets (PLT) >100/µl
6. Creatinin clearance > 1 ml/sec
7. Liver function test > 1.5 fold of upper normal level (UNL)
8. Bilirubin < 22 µmol/l
9. Informed consent
10. No participation in another trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Second malignoma in the history other than basalioma
2. Central nervous system (CNS) lymphoma
3. Respiratory failure

4. Heart failure [New York Heart Association (NYHA) stage 3-4, ejection fraction < 30 %]
5. Severe neurological / psychiatric disease
6. Pregnancy, ineffective contraception
7. Preceding kidney transplantation
8. Positive Human immunodeficiency virus (HIV) test
9. Active viral hepatitis
10. Bacterial infection

Date of first enrolment
01/08/2004

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Germany

Study participating centre
Marienstr. 90
Hannover
Germany
30171

Sponsor information

Organisation
Eastern German Study Group for Haematology and Oncology (OSHO) (Germany)

Sponsor details
Ostdeutsche Studiengruppe für Hämatologie und Onkologie e.V.
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Sponsor type
Research organisation

ROR
https://ror.org/028hv5492

Funder(s)

Funder type
Government

Funder Name
German Health Insurance System (Germany)

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