Purpose

The main purpose of the PETAL trial is to determine whether patients with aggressive non-Hodgkin's lymphomas with a persistently positive PET scan after two cycles of chemotherapy benefit from a change of the treatment protocol.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymphoma, High-grade</td>
<td>D rug: (R-)CHOP protocol</td>
<td>Phase III</td>
</tr>
<tr>
<td></td>
<td>D rug: B-ALL protocol</td>
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</tbody>
</table>

Study Type: Interventional

Study Design: Allocation: Randomized

Endpoint Classification: Efficacy Study

Intervention Model: Parallel Assignment

Masking: Open Label

Primary Purpose: Treatment

Official Title: Positron Emission Tomography Guided Therapy of Aggressive Non-Hodgkin's Lymphomas

Resource links provided by NLM:

- MedlinePlus related topics: Lymphoma, Nuclear Scans
- Drug Information available for: Cyclophosphamide, Prednisone, Vincristine, Doxorubicin
- U.S. FDA Resources

Further study details as provided by University Hospital, Essen:

Primary Outcome Measures:
- Time to treatment failure [ Time Frame: Two years ] [ Designated as safety issue: No ]

Secondary Outcome Measures:
- Response rate, overall survival, disease-free survival, toxicity, quality of life [ Time Frame: Two years ] [ Designated as safety issue: No ]

Estimated Enrollment: 696

Start Date: November 2007

Estimated Study Completion Date: December 2014

Estimated Primary Completion Date: June 2014 (Final data collection date for primary outcome measure)

Arm | Assigned Interventions
---|---
Active Comparator: B1 | Six cycles of the (R-)CHOP regimen. Drug: (R-)CHOP protocol. Patients with a persistently positive interim-PET scan assigned to arm B1 will receive another six cycles of the (R-)CHOP regimen (rituximab, cyclophosphamide, doxorubicine, vincristine, prednisone).


Active Comparator: A1 | Four cycles of the (R-)CHOP regimen. Drug: (R-)CHOP protocol. Patients with a negative interim-PET scan assigned to arm A1 will receive another four cycles of the (R-)CHOP regimen (rituximab, cyclophosphamide, doxorubicine, vincristine, prednisone) plus two additional doses rituximab.

Active Comparator: A2 | Four cycles of the (R-)CHOP regimen plus two additional doses rituximab. Drug: (R-)CHOP protocol. Patients with a negative interim-PET scan assigned to arm A2 will receive another four cycles of the (R-)CHOP regimen (rituximab, cyclophosphamide, doxorubicine, vincristine, prednisone) plus two additional doses rituximab.

Detailed Description:

Positron emission tomography performed after two cycles of (R-)CHOP chemotherapy (interim-PET) has been shown to predict long-term outcome in patients with aggressive non-Hodgkin's lymphomas. Patients with early normalization of pathological PET findings have an excellent prognosis, while patients with a persistently pathological PET scan have a high risk of non-response or relapse.

Patients with a negative interim-PET scan (part A of the trial) will be randomized to receive either another four cycles of the (R-)CHOP regimen (arm A1) or four cycles of the (R-)CHOP regimen plus two additional doses of rituximab (arm A2).

Patients with a persistently positive interim-PET scan (part B of the trial) will be randomized to either continue treatment with another six (R-)CHOP cycles (arm B1) or switch to an alternative protocol used for the treatment of Burkitt's lymphoma (arm B2: six blocks according to the so-called B-ALL protocol of the German ALL study group).

Patients refractory to or relapsing within two years after treatment according to parts A or B of the trial will receive age-adapted salvage protocols (patients < 60 years: high-dose chemotherapy with autologous stem cell transplantation; patients > 60 years: (R-)ESHAP protocol)(part C of the trial).
Eligibility

Inclusion Criteria:
- Aggressive B-cell or T-cell non-Hodgkin's lymphoma
- Pathological pre-treatment PET scan
- Performance status ECOG 0-3
- Age 18 - 80 years
- Ability to understand the purpose of the study and act accordingly
- Willingness to use adequate contraception
- Informed consent

Exclusion Criteria:
- Burkitt's lymphoma
- Primary central nervous system lymphoma
- Previous chemo- and/or radiotherapy
- Other cancer within preceding 5 years
- HIV infection, active viral hepatitis or other uncontrolled infection
- Other medical conditions precluding administration of planned therapy
- Pregnancy or lactation

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00554164

Contacts

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Sponsors and Collaborators

University Hospital, Essen
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Investigators

Principal Investigator: Ulrich Duehrsen, Prof. Dr. Department of Hematology, University Hospital Essen, Hufelandstrasse 55, 45122 Essen, Germany

More Information

No publications provided by University Hospital, Essen

Additional publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):


Keywords provided by University Hospital, Essen:
- Aggressive non-Hodgkin's lymphoma
- Positron emission tomography
- Chemotherapy

Additional relevant MeSH terms:
- Aggression
- Lymphoma
- Lymphoma, Non-Hodgkin
- Behavioral Symptoms
- Neoplasms by Histologic Type
- Neoplasms
- Lymphoproliferative Disorders
- Lymphatic Diseases
- Immunoproliferative Disorders
- Immune System Diseases
- Cyclophosphamide
- Doxorubicin
- Prednisone
- Vincristine
- Immunosuppressive Agents

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