Aim:

The purpose of this study is to determine efficacy and safety of the monoclonal antibody MabCampath® (alemtuzumab) combined with chemotherapy in the treatment of T-cell lymphoma.

Table:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymphoma, T-Cell, Peripheral</td>
<td>Drug: CHOP14 chemotherapy (cyclophosphamide, hydroxydaunorubicin, vincristin, prednisol) plus G-CSF, combined with alemtuzumab/CHOP14 chemotherapy (see specification under Arm B) plus G-CSF</td>
</tr>
</tbody>
</table>

Study Design:

- Interventional
- Allocation: Randomized
- Endpoint Classification: Efficacy Study
- Intervention Model: Parallel Assignment
- Masking: Open Label
- Primary Purpose: Treatment

Official Title:

A Randomized Phase III Study to Evaluate the Efficacy of Chemoimmunotherapy With the Monoclonal Antibody Campath-1H (Alemtuzumab) Given in Combination With 2-weekly CHOP Versus 2-weekly CHOP Alone and Consolidated by Autologous Stem Cell Transplantation in Young Patients With Previously Untreated Systemic Peripheral T-cell Lymphomas

Resource links provided by NLM:

MedlinePlus related topics: Cancer, Lymphoma

Drug Information available for: Alemtuzumab

U.S. FDA Resources

Further study details as provided by University of Aarhus:

Primary Outcome Measures:

- Event-free Survival [Time Frame: The EFS is defined by the time between day of randomization until an event occurs, up to 96 months] [Designated as safety issue: No]

Secondary Outcome Measures:

- Overall survival [Time Frame: From the time of randomization to date of last follow-up or death, up to 96 months] [Designated as safety issue: Yes]
- Overall response rate [Time Frame: from date of randomization to date of primary response assessment, up to 96 months] [Designated as safety issue: No]
- Overall response rate related to the CD5 expression [Time Frame: From date of randomization to date of primary response assessment, up to 96 months] [Designated as safety issue: No]
- Tumor control or time-to-progression [Time Frame: From randomization to last follow-up or time of disease progression, up to 96 months] [Designated as safety issue: No]
- Safety measured as number of adverse events (AEs) and serious adverse events (SAEs) [Time Frame: From randomization to closure of study, up to 96 months] [Designated as safety issue: Yes]
- Feasibility of successful stem cell harvest i.e. >/ =2E6 CD34 positive cells [Time Frame: From start of priming regimen to time of assessment of stem cell harvest, up to 96 months] [Designated as safety issue: Yes]

Estimated Enrollment: 308

Study Start Date: June 2008

Estimated Study Completion Date: December 2016

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

Arm Details:

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active Comparator:</td>
<td>Drug: CHOP14 chemotherapy (cyclophosphamide, hydroxydaunorubicin, vincristin, prednisol) plus G-CSF, combined with alemtuzumab</td>
</tr>
<tr>
<td>Arm A</td>
<td>CHOP14 chemotherapy (cyclophosphamide, hydroxydaunorubicin, vincristin, prednisol) plus G-CSF, combined with alemtuzumab</td>
</tr>
<tr>
<td></td>
<td>6 cycles of CHOP every 2 weeks</td>
</tr>
<tr>
<td>Experimental: Arm B</td>
<td>Drug: CHOP14 chemotherapy (cyclophosphamide, hydroxydaunorubicin, vincristin, prednisol) plus G-CSF, combined with alemtuzumab</td>
</tr>
<tr>
<td></td>
<td>Cyclophosphamide 750 mg/m² i.v. on day 1 Hydroxydaunorubicin 50 mg/m² i.v. on day 1 Vincristin 1 mg/m² i.v. day 1 (max. 2 mg/m²)</td>
</tr>
<tr>
<td></td>
<td>Prednisone 50 mg/m² p.o. day 1 to 5 Alemizumab 30 mg s.c.on day 1 of CHOP-14 cycles 1-4</td>
</tr>
</tbody>
</table>

Detailed Description:

First International phase III T-cell lymphoma study. Indication: Newly diagnosed non-cumulative peripheral T-cell lymphoma. Study objectives: Determination of the efficacy and safety of the monoclonal antibody MabCampath® (alemtuzumab) combined with two-weekly CHOP supported by G-CSF Primary Endpoint: Event-Free-Survival (EFS) Study Design: International open-label, multicentre, randomized Phase III Study

Study Medication: Patients are randomized to six cycles of two-weekly CHOP plus G-CSF with or without alemtuzumab given subcutaneously 30 mg day 1 in combination with chemotherapy cycles 1-4. Patients in CR, CRu and PR after the 6 cycles of CHOP14 combined or not with alemtuzumab will receive a consolidation with high-dose chemotherapy followed by autologous stem cell transplantation.

Patient Population: Patients > 18 yrs with newly diagnosed non-cumulative, non-leukemic PTCL, except alk-protein positive and negative anaplastic large cell lymphoma. Planned Sample Size: 308 young patients (18-60 yrs) registered and randomized Total Number of Centers: This study will be proposed to main European and Australian Study Groups.

http://clinicaltrials.gov/ct2/show/NCT00646854

22.02.2012
Eligibility

**Ages Eligible for Study:** 18 Years to 60 Years

**Genders Eligible for Study:** Both

**Accepts Healthy Volunteers:** No

**Criteria**

**Inclusion criteria:**
- Previously untreated patients with newly diagnosed peripheral T-cell lymphoma of stage I bulk (≥ 7.5 cm) and stages II to IV.
- Patients with a confirmed histologic diagnosis of peripheral T-cell NHL according to the WHO classification:
  - Peripheral T-cell lymphoma, unspecified (PTCL NOS)
  - Angioimmunoblastic T-cell lymphoma
  - Enteropathy-type T-cell lymphoma
  - Subcutaneous panniculitis-like T-NHL (gamma-delta T-cell lymphoma)
  - Hepatosplenic T-cell lymphoma
  - Extramedullary NK/T-cell lymphoma, nasal type
- Age 18-60 years at time of randomization
- Life expectancy of 3 months or longer
- ECOG performance status (PS) 0, 1 or 2 at the time of randomization. However, PS 3 will be acceptable if lymphoma-related
- Measurable disease (defined as at least one lesion with two measurable perpendicular diameters of which at least one should be ≥ 15 mm).
- Written informed consent

**Exclusion Criteria:**
- Patients with NK/T-NHL of the following type:
  - Precursor T cell lymphoblastic lymphoma/leukemia
  - All mature T cell leukemias (T-PLL, ATLL, NK cell leukemia, T-LGL, HTLV1-pos ATL)
  - Histologically positive for CD52 expression
  - Concurrent severe and/or uncontrolled medical disease (e.g. uncontrolled diabetes, congestive heart failure, myocardial infarction within 6 months prior to the study, unstable and uncontrolled hypertension, chronic renal disease, or active uncontrolled infection), which could compromise participation in the study
- Known hypersensitivity to murine or chimeric antibodies or proteins
- Severe cardiac dysfunction (NYHA classification II-IV, Appendix H) or LVEF < 45 %
- Significant renal dysfunction, i.e. serum creatinin >2 times upper normal level (UNL), unless related to NHL
- Significant hepatic dysfunction (total bilirubin >2 times UNL or transaminases > 2.5 times UNL), unless related to NHL
- Impaired pulmonary functions; in this case, the patient is to be excluded if the resultant pulmonary function test shows FEV1<50% or a diffusion capacity <50% of the reference values
- Suspected or documented Central Nervous System involvement by NHL
- Patients known to be HIV-positive
- Patients with active, uncontrolled infections, especially known seropositivity for HCV or HbsAg
- Patients with uncontrolled asthma or allergy, requiring systemic steroid treatment
- Prior treatment with chemotherapy, radiotherapy or immunotherapy for this lymphoma, except local radiotherapy in case of extranodal NK/T cell lymphoma, nasal or nasal type
- History of active cancer during the past 5 years, except basal carcinoma of the skin or stage 0 cervical carcinoma
- Unwillingness or inability to comply with the protocol
- Simultaneous participation in any other study protocol
- Pregnant and nursing women (Women of childbearing potential should use safe anticonceptives) Contraceptive pills, intrauterine devices, injection of prolonged gestagen, subdermal implantation, hormonal vaginal devices and transdermal patches are considered as safe contraceptive methods.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00646854

**Contacts**

Contact: Francesco d’Amore, Prof + 45 8949 7567 frandamo@rm.dk

**Sponsors and Collaborators**

GCP-unit at Aarhus University Hospital, Aarhus, Denmark

**Investigators**

Principal Investigator: Francesco d’Amore, Prof Dept. of Hematology, Århus University Hospital, Denmark

More Information

No publications provided

**Responsible Party:** University of Aarhus ( Aarhus University Hospital )

**ClinicalTrials.gov Identifier:** NCT00646854

**Other Study ID Numbers:** 20060613271

**Study First Received:** February 14, 2008

**Last Updated:** September 15, 2011

**Health Authority:** Denmark: Danish Medicines Agency; Denmark: Ethics Committee; Denmark: Danish Dataprotection Agency

**Keywords provided by University of Aarhus:** Lymphoma, T-Cell, Lymphoma, T-Cell, Peripheral, CD52 expression, CD52,

**Additional relevant MeSH terms:** Lymphoma, Lymphoma, T-Cell, Lymphoma, T-Cell, Peripheral, Neoplasms by Histologic Type, Neoplasms, Lymphoproiferative Disorders, Lymphatic Diseases, Immunoproliferative Disorders, Immune System Diseases, Lymphoma, Non-Hodgkin

**Pharmacologic Actions:** Docetaxel, Immunosuppressive Agents, Immunologic Factors, Physical Effects of Drugs, Antihistaminic Agents, Antineoplastic Agents, Alkylating Agents, Molecular Mechanisms of Pharmacological Action

**Therapeutic Uses:** Drug-Related Chemistry, Drug-Related Chemistry, Drug-Related Chemistry, Drug-Related Chemistry