Rituximab and Combination Chemotherapy With or Without Radiation Therapy in Treating Patients With B-Cell Non-Hodgkin's Lymphoma

This study is currently recruiting participants.
Verified July 2009 by National Cancer Institute (NCI)

First Received on January 16, 2006. Last Updated on April 16, 2010

Purpose

RATIONALE: Monoclonal antibodies, such as rituximab, can block cancer growth in different ways. Some find cancer cells and kill them or carry cancer-killing substances to them. Others interfere with the ability of cancer cells to grow and spread. Drugs used in chemotherapy, such as cyclophosphamide, doxorubicin hydrochloride, vincristine, and prednisone, work in different ways to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. Radiation therapy uses high-energy x-rays to kill cancer cells. Giving rituximab and combination chemotherapy together with radiation therapy may kill more cancer cells. It is not yet known which schedule of rituximab and combination chemotherapy is more effective when given with or without radiation therapy in treating non-Hodgkin's lymphoma.

PURPOSE: This randomized phase III trial is studying two different schedules of rituximab and combination chemotherapy with or without radiation therapy to compare how well they work in treating patients with aggressive B-cell non-Hodgkin's lymphoma.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
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<tbody>
<tr>
<td>Lymphoma</td>
<td>Biological: filgrastim</td>
<td>Phase 3</td>
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<tr>
<td></td>
<td>Biological: rituximab</td>
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<tr>
<td></td>
<td>Drug: cyclophosphamide</td>
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<td></td>
<td>Drug: doxorubicin hydrochloride</td>
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<td></td>
<td>Drug: prednisone</td>
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<td>Drug: vincristine sulfate</td>
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<td>Radiation: radiation therapy</td>
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</tbody>
</table>

Resource links provided by NLM:

MedlinePlus related topics: Cancer Lymphoma

Doxorubicin Doxorubicin hydrochloride Filgrastim Lenograstim Granulocyte colony-stimulating factor Rituximab
Primary Outcome Measures:
- Time to treatment failure (TTF) measured from day 1 of course 1 of cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) therapy up to 3 years on study with life-long follow-up [Designated as safety issue: No]

Secondary Outcome Measures:
- Complete response (CR) rate until first relapse [Designated as safety issue: No]
- Progression rate during treatment [Designated as safety issue: No]
- Survival [Designated as safety issue: No]
- Tumor control measured from day 1 of course 1 of CHOP therapy (non-tumor related events are censored) [Designated as safety issue: No]
- Disease-free survival measured from day 1 of course 1 of CHOP therapy [Designated as safety issue: No]
- Relapse-free survival of patients with complete response (CR) or unconfirmed complete response (CRu) following complete immunochemotherapy [Designated as safety issue: No]
- Safety (adverse events, serious adverse events) assessed at 3 months after completion of study treatment [Designated as safety issue: Yes]
- Consolidating radiotherapy [Designated as safety issue: No]
- No mucosa-associated lymphoid tissue (MALT) lymphoma
- No CNS involvement of lymphoma (intracerebral, meningeal, or intraspinal)

**PATIENT CHARACTERISTICS:**
- ECOG performance status 0-2
- Platelet count ≥ 100,000/mm³
- WBC ≥ 2,500/mm³
- No known hypersensitivity to the study medications
- No known HIV-positivity
- No active hepatitis infection
- Not pregnant or lactating
- Negative pregnancy test
- No other malignancy within the past 5 years except carcinoma in situ or basal cell skin cancer
- No impaired left ventricular function
- No severe cardiac arrhythmias
- No other impaired organ function
- No other serious disorder

**PRIOR CONCURRENT THERAPY:**
- No prior chemotherapy or radiotherapy
- No prior immunosuppressive treatment with cytostatics
- No concurrent participation in other treatment studies

**Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier: NCT00278408

**Show 79 Study Locations**

**Sponsors and Collaborators**

German High-Grade Non-Hodgkin's Lymphoma Study Group

**Investigators**

Study Chair: Michael G.M. Pfundschuh, MD Universitätsklinikum des Saarlandes

**More Information**

Additional Information:

Clinical trial summary from the National Cancer Institute's PDQ® database

No publications provided

ClinicalTrials.gov Identifier: NCT00278408 History of Changes

Other Study ID Numbers: CDR0000459796, DSHNHL-2004-3, EUDRACT-2005-005218-19, EU-205111

Study First Received: January 16, 2006

Last Updated: April 16, 2010

Health Authority: Unspecified

Keywords provided by National Cancer Institute (NCI):
- contiguous stage II grade 3 follicular lymphoma
- noncontiguous stage II grade 3 follicular lymphoma
- stage I grade 3 follicular lymphoma
- stage III grade 3 follicular lymphoma
- stage IV grade 3 follicular lymphoma
- contiguous stage II adult diffuse large cell lymphoma
- contiguous stage II adult diffuse mixed cell lymphoma
- noncontiguous stage II adult diffuse large cell lymphoma
- noncontiguous stage II adult diffuse mixed cell lymphoma
- nodal marginal zone B-cell lymphoma
- anaplastic large cell lymphoma
- contiguous stage II adult immunoblastic large cell lymphoma
- noncontiguous stage II adult immunoblastic large cell lymphoma
- stage I adult immunoblastic large cell lymphoma
- stage III adult immunoblastic large cell lymphoma
- stage IV adult immunoblastic large cell lymphoma
- contiguous stage II adult Burkitt lymphoma
- contiguous stage II mantle cell lymphoma