Pilot Trial of Intravenous Vitamin C in Refractory Non-Hodgkin Lymphoma (NHL)

This study is currently recruiting participants.
Verified by Thomas Jefferson University, April 2009

First Received: February 21, 2008 Last Updated: April 27, 2009 History of Changes

Sponsor:	Thomas Jefferson University
Information provided by:	Thomas Jefferson University
ClinicalTrials.gov Identifier:	NCT00626444

Purpose

Eligible candidates will be adults with aggressive or very aggressive NHL (WHO classification diagnosis confirmed by histological tumor examination). Patients must have failed one or more prior NHL chemotherapy or antibody therapy with curative intent, and the disease must not have progressed within 60 days of last therapy. In addition, patients must not be candidates for potentially curative therapy, such as HSCT, or they must have refused these alternative therapies. Full inclusion/exclusion criteria are available. History and physical examination, and laboratory and imaging analyses will be done within 14 days prior to registration. Intravenous ascorbic acid will be given in a dose based on the plasma vitamin C level to reach a level in the range of 300 to 350 mg/dL. Vitamin C infusions will be given three times a week on a schedule that allows at least 24 hours between each infusion, for a total of ten weeks (30 infusions). If disease progression occurs before or at the ten week assessment, then we discontinue protocol, based on futility. Toxicity and adverse events also will result in immediate discontinuation (details available in full protocol). If there is lack of disease progression or disease improvement, proceed and reassess again at 10 week intervals, for a total of three 10 week intervals. Initial criteria are based upon the criteria from the International Workshop to Standardize Criteria for Non-Hodgkin's Lymphoma (Cheson et al., Report of an international workshop to standardize response criteria for non-Hodgkin's lymphoma, Journal of Clinical Oncology, 1999, Vol. 17, No4, 1244-1253); response for this study will utilize PET in accordance with revised criteria (Cheson et al. Revised response criteria for malignant lymphoma. J of Clin Oncol 2007; 25(5): 579-586). We select 20 patients as an appropriate study size to evaluate a true response rate to therapy, compared to just the observed response.

Condition	Intervention	Phase
Non-Hodgkin Lymphoma	Drug: Intravenous vitamin C	Phase II

Study Type: Interventional
Study Design: Control: Uncontrolled
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Phase II Trial of High Dose Intravenous Vitamin C in Patients With Refractory Non-Hodgkin Lymphoma

Resource links provided by NLM:

MedlinePlus related topics: Lymphoma Vitamin C

Drug Information available for: Ascorbic acid

U.S. FDA Resources

Further study details as provided by Thomas Jefferson University:

Primary Outcome Measures:

- Progression-free survival [Time Frame: 10 weeks] [Designated as safety issue: No]

Secondary Outcome Measures:

- Duration of response [Time Frame: 10 weeks] [Designated as safety issue: No]

Estimated Enrollment:	20
Study Start Date:	February 2008
Estimated Study Completion Date:	January 2010
Estimated Primary Completion Date:	January 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
1: Experimental Intravenous vitamin C	Drug: Intravenous vitamin C Up to 100 gms of intravenous vitamin C, three times per week for 10 weeks.

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Age greater than 18 years old
- Aggressive or very aggressive NHL
- Failed one or more therapies
- Patients must not have progressed within 60 days of last therapy
- Not received allogeneic stem cell transplant
- No reasonable standard therapeutic options available
- Glucose 6 phosphate dehydrogenase status normal
- ECOG performance status 0-2
- Normal creatinine and transaminase
- Women of child-bearing potential confirm negative pregnancy test

Exclusion Criteria:

- Significant co-morbid disorders
- Significant psychiatric symptoms
- Smoking
- Excessive alcohol or drug use
- Enrollment in other experimental therapy
- Active infection
- Patients experiencing ongoing response to recent treatments
- Patients who have received chemotherapy within 30 days or biological therapy within 6 weeks

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00626444

Contacts

Contact: Joel S Edman, DSc 215-955-2839 joel.edman@jefferson.edu

Locations

United States, Pennsylvania

Jefferson-Myrna Brind Center of Integrative Medicine **Recruiting**
Philadelphia, Pennsylvania, United States, 19107
Principal Investigator: Daniel A Monti, MD

Sponsors and Collaborators

Thomas Jefferson University

More Information

No publications provided

Responsible Party:	Thomas Jefferson University (Daniel A. Monti, MD)
ClinicalTrials.gov Identifier:	NCT00626444 History of Changes
Other Study ID Numbers:	IND-77486
Study First Received:	February 21, 2008
Last Updated:	April 27, 2009
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Lymphoma	Vitamins
Lymphoma, Non-Hodgkin	Antioxidants
Neoplasms by Histologic Type	Molecular Mechanisms of Pharmacological Action
Neoplasms	Pharmacologic Actions
Lymphoproliferative Disorders	Protective Agents
Lymphatic Diseases	Physiological Effects of Drugs
Immunoproliferative Disorders	Micronutrients
Immune System Diseases	Growth Substances
Ascorbic Acid	

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