Trial record **4 of 77** for: Interferon alfa-2b AND interferon alfa-2b AND Intron A | Melanoma

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A Phase II Study of an Anti-Tumor Immunotherapy Regimen Comprised of Pegylated Interferon-Alpha 2b and HyperAcute Melanoma Vaccine for Subjects With Advanced Melanoma

ClinicalTrials.gov Identifier: NCT00746746

Recruitment Status : Unknown
Verified September 2008 by Ochsner Health System.
Recruitment status was: Active, not recruiting
First Posted : September 4, 2008
Last Update Posted : January 13, 2011

Sponsor:
Ochsner Health System

Collaborator:
NewLink Genetics Corporation

Information provided by:
Ochsner Health System

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

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Brief Summary:

The purpose of this study is to determine the safety of giving subjects with advanced, recurrent or refractory melanoma the HyperAcute® Melanoma vaccine with a variant of a drug, called **Interferon** (PEG-**Intron®**) that is specially formulated to be given on a weekly basis (instead of daily). The study vaccine (HyperAcute®-Melanoma) is made from three types of human melanoma cell lines (grown in the laboratory) in which the genes have been slightly changed. This clinical study will try to discover the safety of the study vaccine combined with PEG-**Intron®**, its side effects and the potential benefits, if any.

Condition or disease	Intervention/treatment	Phase
Melanoma	Biological: HyperAcute vaccine Drug: Pegylated **Interferon-Alpha 2b**	Phase 2

Detailed Description:

This study will look at the anti-tumor vaccine effect, side effects and toxicity of the HyperAcute® Vaccine with PEG-Intron®. It is hoped that the immune system's response to these genetically engineered melanoma cells and PEG-Intron® will cause a reaction that will make it react to and attack and kill the melanoma cells and keep it from growing, possibly causing the tumors to shrink.

Patients that are eligible are 19 years or older and have been diagnosed with advanced, treatment resistant or recurrent melanoma, an aggressive usually pigmented form of skin cancer.

Study Design

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Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	30 participants
Allocation:	Non-Randomized
Intervention Model:	Single Group Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	A Phase II Study of an Anti-Tumor Immunotherapy Regimen Comprised of Pegylated **Interferon-Alpha 2b** (PEG-**Intron**)and HyperAcute **Melanoma** Vaccine for Subjects With Advanced **Melanoma**
Study Start Date :	June 2008
Estimated Primary Completion Date :	June 2010
Estimated Study Completion Date :	June 2011

Resource links provided by the National Library of Medicine NIH NLM

Genetics Home Reference related topics: Melanoma

MedlinePlus related topics: Melanoma

Drug Information available for: Interferon Interferon Alfa-2a Interferon Alfa-2b Peginterferon Alfa-2b

Genetic and Rare Diseases Information Center resources: Neuroendocrine Tumor Neuroepithelioma

U.S. FDA Resources

Arms and Interventions

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Intervention Details:

- Biological: HyperAcute vaccine

  1.8 mL weekly
- Drug: Pegylated **Interferon-Alpha 2b**

  6.0 mcg/kg weekly

  Other Name: PEG-**Intron**

Outcome Measures

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Primary Outcome Measures :

1. To conduct scientific studies of patient tumor and peripheral blood samples to determine the mechanism of any observed anti-tumor effect involving the immune responses to the HyperAcute® vaccine alone & combined with PEG-**Intron** [Time Frame: 2 years]

Secondary Outcome Measures :

1. To determine the safety and response rate of the administration of the HyperAcute®-Melanoma Vaccine combined with PEG-**Intron®** into patients with recurrent, refractory, metastatic, or high risk of recurrence melanoma [Time Frame: 2 years]

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	19 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- 19 years or older
- Histological diagnosis of melanoma
- AJCC Stage IIIC (any T, N1b, N2b, N3, M0) or Stage IV (any T, and N, M1), metastatic, progressive, refractory, recurrent or high risk of recurrence melanoma.
- Expected survival of more than 6 months
- Adequate organ function
- Measurable or non-measurable disease
- Must have negative serologies for Hepatitis B and C and HIV prior to entering study
- Must be more than 4 weeks since major surgery, radiotherapy, chemotherapy or biotherapy/targeted therapies
- Male and female subjects of child producing potential must agree to use contraception or avoidance pregnancy measures while enrolled on the study and for one month after the last immunization.

Exclusion Criteria:

- Active CNS metastases or carcinomatous meningitis
- Hypercalcemia
- Pregnant or nursing women
- Other malignancy within five years
- History of organ transplant or current active immunosuppressive therapy
- Subjects taking systemic corticosteroid therapy
- Active infection or antibiotics within 1-week prior to study
- Uncontrolled or significant congestive heart failure, myocardial infarction, ventricular arrhythmias or pulmonary dysfunction
- Autoimmune disease
- A known allergy to any component of the HyperAcute vaccine or PEG-Intron
- Patients having undergone splenectomy
- Patients with sickle-cell anemia or thalassemia major.

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT00746746***

Locations

United States, Louisiana

Ochsner Health System
New Orleans, Louisiana, United States, 70121

Sponsors and Collaborators

Ochsner Health System

NewLink Genetics Corporation

Investigators

Principal Investigator: Adam I Riker, MD Ochsner Health System

More Information

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Additional Information:

Ochsner Health System website

Responsible Party:	Adam I. Riker, M.D. Medical Director of Cancer Services, Ochsner Cancer Institute
ClinicalTrials.gov Identifier:	NCT00746746 History of Changes
Other Study ID Numbers:	USA-MCI-01 IND# 13647
First Posted:	September 4, 2008 Key Record Dates
Last Update Posted:	January 13, 2011
Last Verified:	September 2008

Keywords provided by Ochsner Health System:
Advanced **Melanoma**

Additional relevant MeSH terms:

Melanoma
Nevi and **Melanomas**
Interferon-alpha
Interferons
Peginterferon **alfa-2b**
Neuroendocrine Tumors
Neuroectodermal Tumors
Neoplasms, Germ Cell and Embryonal
Neoplasms by Histologic Type
Neoplasms
Neoplasms, Nerve Tissue
Vaccines
Immunologic Factors
Physiological Effects of Drugs
Antineoplastic Agents
Antiviral Agents
Anti-Infective Agents