

Trial record **40 of 77** for: Interferon alfa-2b AND interferon alfa-2b AND Intron A | Melanoma

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Cognitive Effects of Interferon in Patients With Melanoma

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators.

⚠ Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT02074605

[Recruitment Status](#) ⓘ : Completed

[First Posted](#) ⓘ : February 28, 2014

[Last Update Posted](#) ⓘ : February 28, 2014

Sponsor:

University of Arizona

Information provided by (Responsible Party):

Daniel Combs, University of Arizona

Study Details

Tabular View

No Results Posted

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Study Description

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Brief Summary:

Interferon alpha is the only approved adjuvant biologic therapy for individuals diagnosed with high risk malignant melanoma (stage 2 or 3). There is evidence that **interferon** has some adverse cognitive effects on patients, but there are limited data. The investigators hypothesis is that compared to patients with melanoma who do not receive **interferon**, patients who have melanoma and are treated with **interferon** will show an objective decrease in performance on neurocognitive assessment.

This study will enroll patients with melanoma who qualify for **interferon**, and either decide to undergo **interferon** treatment or choose watchful waiting instead. All patients will be assessed with a cognitive testing battery twice. Observation patients will undergo testing at their first appointment in which they consent to the study, as well as at their next physician visit, approximately 3 months from the first visit.

Interferon patients will be tested immediately prior to starting **interferon**, as well as immediately after completing high dose **interferon**.

Condition or disease ⓘ	Intervention/treatment ⓘ
Melanoma	Biological: Interferon alpha

Study Design

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[Study Type](#) ⓘ : Observational

Actual [Enrollment](#) ⓘ : 36 participants

Observational Model: Case Control


Time Perspective: Prospective

Official Title: A Pilot Study of Neurocognitive Function in Patients Treated With Adjuvant **Interferon Alpha-2b** for High-Risk **Melanoma**

[Study Start Date ⓘ](#) : July 2008

[Actual Primary Completion Date ⓘ](#) : May 2010

[Actual Study Completion Date ⓘ](#) : May 2010

Resource links provided by the National Library of Medicine 

[Genetics Home Reference](#) related topics: [Melanoma](#)

[MedlinePlus](#) related topics: [Melanoma](#)

[Drug Information](#) available for: [Interferon](#) [Interferon Alfa-2a](#)

[Genetic and Rare Diseases Information Center](#) resources:
[Neuroendocrine Tumor](#) [Neuroepithelioma](#)

[U.S. FDA Resources](#)

Groups and Cohorts

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Group/Cohort ⓘ	Intervention/treatment ⓘ
<p>Observation</p> <p>Patients with melanoma who qualify for interferon treatment, but choose not to receive it.</p>	
<p>Interferon alpha</p> <p>Patients who receive high dose interferon alpha for 4 weeks</p>	<p>Biological: Interferon alpha</p> <p>Other Name: Intron-A</p>

Outcome Measures


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[Primary Outcome Measures ⓘ](#) :

- Change in cognitive function [Time Frame: 1 month]
 Cognitive function as assessed by a brief neurocognitive testing battery

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: 18 Years and older (Adult, Older Adult)
 Sexes Eligible for Study: All
 Accepts Healthy Volunteers: No
 Sampling Method: Non-Probability Sample

Study Population

Patients in one of these categories:

1. Are to receive adjuvant treatment with interferon alpha-2b after complete surgical resection of high risk melanoma.
2. Have had a complete surgical resection of high risk melanoma, but have elected not to receive interferon alpha-2b and will be observed for disease progression only.

Criteria

Inclusion Criteria:

- Patients diagnosed with high risk malignant melanoma (defined as American Joint Committee on Cancer Stage IIb or greater) electing to undergo treatment with either adjuvant interferon alpha-2b, or observation only.
- Age 18 years or older.
- Karnofsky performance status greater than 60.
- Fluent English speaker.

Exclusion Criteria:

- History of neurologic or psychiatric disease that will affect patient's ability to complete protocol tests.
- Clinical or radiological evidence of brain metastasis.
- Any condition, which in the opinion of the investigator makes the subject unsuitable for study participation.

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): **NCT02074605***

Locations

United States, Arizona

University of Arizona

Tucson, Arizona, United States, 85724

Sponsors and Collaborators

University of Arizona

Investigators

Principal Investigator: Daniel Combs, MD University of Arizona

More Information

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Publications of Results:

Combs D, Baker A, Jordan S, Morgan S, Pestana L, Herring A, Jeter J, Hersh E, Cranmer LD. Screening tools for interferon-related cognitive decline in melanoma patients. *J Clin Oncol* 28:7s, May 2010 (suppl; abstr 8539). Abstract.

Combs D, Baker A, Herring A, Trevor K, Jeter J, Cranmer L. Effects of high dose interferon on memory in melanoma patients. *Pigment Cell and Melanoma Research* 22(6):866, Dec 2009. Abstract.

Responsible Party: Daniel Combs, Clinical Assistant, University of Arizona

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Keywords provided by Daniel Combs, University of Arizona:

Melanoma

Interferon

Cognition

Additional relevant MeSH terms:

Melanoma

Nevi and **Melanomas**

Interferons

Interferon-alpha

Neuroendocrine Tumors

Neuroectodermal Tumors

Neoplasms, Germ Cell and Embryonal

Neoplasms by Histologic Type

Neoplasms

Neoplasms, Nerve Tissue

Antineoplastic Agents

Antiviral Agents

Anti-Infective Agents

Immunologic Factors

Physiological Effects of Drugs