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Trial record **38 of 77** for:　Interferon alfa-2b AND interferon alfa-2b AND Intron A | Melanoma

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Phase II Study Incorporating Pegylated Interferon In the Treatment For Children With High-Risk 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: NCT00539591

Recruitment Status ❶ : Completed
First Posted ❶ : October 4, 2007
Results First Posted ❶ : February 27, 2014
Last Update Posted ❶ : March 23, 2017

Sponsor:

St. Jude Children's Research Hospital

Collaborator:

Schering-Plough

Information provided by (Responsible Party):

St. Jude Children's Research Hospital

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Study Description

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Brief Summary:

The main goal of this study is to estimate the tumor response rate of temozolomide administered in combination with peginterferon **alfa-2b** to pediatric patients with unresectable Stage III, metastatic, or recurrent cutaneous melanoma.

Condition or disease ❶	Intervention/treatment ❶	Phase ❶
Malignant **Melanoma**	Drug: Peginterferon **alfa-2b** Drug: Temozolomide Drug: Recombinant **interferon alfa-2b**	Phase 2

Detailed Description:

This study is for children with malignant melanoma and high risk features (at high risk of melanoma returning or spreading to other parts of the body) or who have recurrent disease. The study has two treatment groups based on the stage of the disease. Patients with stage IIC, IIIA or IIIB melanoma whose tumors have been removed by surgery will be treated in study group A. These patients will receive 4 weeks of high dose interferon alfa-2b followed by 48 weeks of peginterferon. Patients with stage IIIC or IV melanoma, stage III melanoma that could not be removed by surgery and those with recurrent disease will be treated in study group B. These patients will receive peginterferon alfa-2b and temozolomide.

Stratum A: Resected Stages IIC, IIIA, and IIIB patients

Induction therapy (weeks 1-4): Subjects will receive recombinant interferon alfa-2b 20 million units/m2 per day intravenously over 20-30 minutes on 5 consecutive days per week for 4 weeks. Subjects will receive peginterferon alfa-2b 1 mcg/kg/week subcutaneously for a total of 48 weeks.

Stratum B: Resected Stage IIIC, unresectable Stage III, Stage IV, and recurrent patients

Stratum B is divided into 2 groups based on the presence (Stratum B1) or absence (Stratum B2) of measurable disease. Subjects will receive 8 weekly doses of peginterferon alfa-2b 0.5 mcg/kg/dose subcutaneously in combination with temozolomide 75mg/m2/dose by mouth daily for 6 weeks followed by 2 week break. The duration of each treatment course will be 8 weeks. Strata B2 (no measurable disease) will proceed with 7 courses as outlined.

Surgery interventions -Associated with both Strata A and B Surgery description: All subjects with initial presentation of melanoma (T1-4) will be treated with primary wide local excision with a minimum of 1cm margin (if anatomically feasible) surrounding the primary lesion or biopsy scar. For lesions with Breslow's thickness of > 1mm or <or= with ulceration or Clark's level IV/V, a 2 cm margin is preferred when anatomically feasible. Subjects with sentinel lymph node(s) positive for disease, will undergo complete lymph node dissection of the involved nodal basin.

Additional objectives include:

- To assess the safety of temozolomide administered in combination with peginterferon α-2b to pediatric patients with resected AJCC Stage IIIC, unresectable Stage III, metastatic, or recurrent cutaneous melanoma (Stratum B).

- To study the feasibility and safety of administering peginterferon α-2b weekly for 48 weeks following an initial induction phase with intravenous high dose interferon α-2b for 4 weeks to pediatric patients with resected thick melanomas (> 4mm) with ulcerations (AJCC Stage IIC) and resected melanomas with regional lymph node metastases (AJCC Stage IIIA and IIIB) (Stratum A).

Study Design

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Study Type ❶ :	Interventional (Clinical Trial)
Actual Enrollment ❶ :	29 participants
Allocation:	Non-Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	Phase II Study Incorporating Pegylated **Interferon** In the Treatment For Children With High-Risk **Melanoma**
Study Start Date ❶ :	October 2007
Actual Primary Completion Date ❶ :	June 2015
Actual Study Completion Date ❶ :	October 2015

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   Temozolomide   Interferon Alfa-2b   Peginterferon Alfa-2b

Genetic and Rare Diseases Information Center resources: Melanoma, Familial   Neuroendocrine Tumor   Neuroepithelioma

U.S. FDA Resources

Arms and Interventions

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Arm ❶	Intervention/treatment ❶

Experimental: Temozolomide/peginterferon **alfa-2b** 　　Stratum B: Resected Stage IIIC, unresectable Stage III, Stage IV, and recurrent patients 　　Stratum B is divided into 2 groups based on the presence (Stratum B1) or absence (Stratum B2) of measurable disease. Subjects will receive 8 weekly doses of peginterferon **alfa-2b** 0.5 mcg/kg/dose subcutaneously (SQ) in combination with temozolomide 75mg/m2/dose by mouth (PO) daily for 6 weeks followed by 2 week break. The duration of each treatment course will be 8 weeks. Strata B2 (no measurable disease) will proceed with 7 courses as outlined.	Drug: Peginterferon **alfa-2b** 　　Given either IV or SQ. Therapeutic drug class: **interferon**. 　　Other Names: 　　　• PEG-**Intron**(R) 　　　• pegylated **interferon alfa-2b** Drug: Temozolomide 　　Given PO. Therapeutic drug class: antineoplastic agent. 　　Other Name: Temodar(R), SCH 52365
Experimental: Peginterferon **alfa-2b**/non-pegylated **interferon alfa-2b** 　　Stratum A: Resected Stages IIC, IIIA, and IIIB patients will receive recombinant **interferon alfa-2b** 20 million units/m2/day intravenously (IV) 5 consecutive days per week for 4 weeks followed by peginterferon **alfa-2b** 1mcg/kg subcutaneously (SQ) once a week for 48 weeks.	Drug: Peginterferon **alfa-2b** 　　Given either IV or SQ. Therapeutic drug class: **interferon**. 　　Other Names: 　　　• PEG-**Intron**(R) 　　　• pegylated **interferon alfa-2b** Drug: Temozolomide 　　Given PO. Therapeutic drug class: antineoplastic agent. 　　Other Name: Temodar(R), SCH 52365 Drug: Recombinant **interferon alfa-2b** 　　Given IV. Therapeutic drug classes: antineoplastic agent,

immunomodulatory agent, **interferon**

Other Names:

- **Intron®**
- non-pegylated **interferon alfa-2b**

Outcome Measures

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[Primary Outcome Measures] ❶ :

1. Tumor Response Rate [Time Frame: 8 weeks]

   Tumor response rate of stratum B1 participants was evaluated after 1 treatment course of temozolomide plus peginterferon α-2b. Complete response (CR) and partial response (PR) confirmed with repeated scan at least 4 weeks apart following completion of course 1 therapy. CR defined as disappearance of all target and non-target lesions with no new lesions detected. If available, no disease must be detected by immunocytology or serum tumor markers. PR defined as at least 30% decrease in disease measurement compared to disease measurement at study entry with no new lesions detected. Progressive disease (PD) defined as at least 20% increase in the disease measurement compared to the smallest disease measurement recorded since start of treatment, or appearance of one or more new lesions. Stable disease defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD compared to smallest disease measurement since start of treatment.

2. Number of Patients Who Experience Toxicity at or Above the Target Toxicity for Strata B1 and B2 [Time Frame: 52 weeks]

   The objective was to assess the safety of temozolomide administered in combination with peginterferon a-2b in Stratum B participants.

   Accrual was suspended any time during therapy if 2 or more of 6, 4 or more of 12, 6 or more of 18, 8 or more of 24, 10 or more of 30 participants experienced target toxicity defined as:

   - Grade 4 non-hematologic (non-hem) toxicity that does not resolve to ≤grade 1 within 2 weeks from the time next dose is due and is determined to be probably or definitely related to protocol therapy
   - Grade 4 non-hem toxicity that is NOT constitutional symptoms (fever, chills, fatigue and/or pain)
   - Grade 3 elevations in creatinine or BUN that are determined to be probably or definitely related to protocol therapy
   - Grade 4 cardiopulmonary toxicity that is determined to be probably or definitely related to protocol therapy
   - Grade 4 mood alteration (suicidal ideation; danger to self or others)

3. Number of Patients Who Experience Toxicity at or Above the Target Toxicity for Stratum A Patients [Time Frame: 52 weeks]

   The objective was to study the feasibility and safety of administering peginterferon a-2b weekly for 48 weeks following the initial induction phase to Stratum A participants.

   Accrual was suspended during the 48-week course if 2 or more of 6, 4 or more of 12, 6 or more of 18, 8 or more of 24, 10 or more of 30 participants experienced target toxicity defined as:

   - Grade 4 non-hematologic (non-hem) toxicity that does not resolve to ≤grade 1 within 2 weeks from the time next dose is due and is determined to be probably or definitely related to protocol therapy
   - Grade 4 non-hem toxicity that is NOT constitutional symptoms (fever, chills, fatigue and/or pain)
   - Grade 3 elevations in creatinine or BUN that are determined to be probably or definitely related to protocol therapy
   - Grade 4 cardiopulmonary toxicity that is determined to be probably or definitely related to protocol therapy
   - Grade 4 mood alteration (suicidal ideation; danger to self or others)

4. Probability of Event-free Survival (EFS) of Stratum A Participants [Time Frame: 3 years from diagnosis]

The probability of EFS was estimated as time to first event (relapse, death or second malignancy). As of April 2016, 21 out of 23 participants had no events. The EFS rate was estimated by Kaplan-Meier method.

Other Outcome Measures:

1. Median Steady State Trough Concentration of Pegylated **Interferon** α-2B [Time Frame: Before first dose, and 24, 96 and 168 hours after dose during weeks 5 and 28]

    The pharmacokinetic (PK) analysis of pegylated α-2b included only patients within Stratum A who had PK studies performed.

    Samples were analyzed for pegylated **interferon** α-2b concentrations by using the VeriKine Human **Interferon** Alpha ELISA Kit following the manufacturer's instructions, and concentration-time data were analyzed by nonlinear-mixed effects modeling as implemented in NONMEM.

2. Area Under the Curve (AUC) of Pegylated **Interferon** α-2B [Time Frame: Before first dose, and 24, 96 and 168 hours after dose during weeks 5 and 28]

    Pharmacokinetic (PK) analysis of pegylated α-2b included only Stratum A patients who had PK studies performed.

    Samples were analyzed for pegylated **interferon** α-2b concentrations by using the VeriKine Human **Interferon** Alpha ELISA Kit following the manufacturer's instructions, and concentration-time data were analyzed by nonlinear-mixed effects modeling as implemented in NONMEM. AUC is given as Time 0 through infinity.

3. α Half Life of Pegylated **Interferon** α-2B [Time Frame: Before first dose, and 24, 96 and 168 hours after dose during weeks 5 and 28]

    Pharmacokinetic (PK) analysis of pegylated α-2b included only Stratum A patients who had PK studies performed.

    Samples were analyzed for pegylated **interferon** α-2b concentrations by using the VeriKine Human **Interferon** Alpha ELISA Kit following the manufacturer's instructions, and concentration-time data were analyzed by nonlinear-mixed effects modeling as implemented in NONMEM.

4. Volume of Central Compartment (Vc) of Pegylated **Interferon** α-2B [Time Frame: Before first dose, and 24, 96 and 168 hours after dose during weeks 5 and 28]

    Pharmacokinetic (PK) analysis of pegylated α-2b included only Stratum A patients who had PK studies performed.

    Samples were analyzed for pegylated **interferon** α-2b concentrations by using the VeriKine Human **Interferon** Alpha ELISA Kit following the manufacturer's instructions, and concentration-time data were analyzed by nonlinear-mixed effects modeling as implemented in NONMEM.

5. Apparent Clearance (CL) of Pegylated **Interferon** α-2B [Time Frame: Before first dose, and 24, 96 and 168 hours after dose during weeks 5 and 28]

    Pharmacokinetic (PK) analysis of pegylated α-2b included only Stratum A patients who had PK studies performed.

    Samples were analyzed for pegylated **interferon** α-2b concentrations by using the VeriKine Human **Interferon** Alpha ELISA Kit following the manufacturer's instructions, and concentration-time data were analyzed by nonlinear-mixed effects modeling as implemented in NONMEM.

6. Area Under the Curve (AUC) of **Interferon** α-2b [Time Frame: Before first dose, and 1, 2, 4, 6, 8, 12, and 24 hours postinfusion]

    Samples were analyzed for **interferon** α-2b concentrations by using the VeriKine Human **Interferon** Alpha ELISA Kit following the manufacturer's instructions, and concentration-time data were analyzed by nonlinear-mixed effects modeling as implemented in NONMEM. AUC is given as Time 0 to infinity.

7. Half-Life of **Interferon** α-2b [Time Frame: Before first dose, and 1, 2, 4, 6, 8, 12, and 24 hours postinfusion]

Samples were analyzed for **interferon** α-2b concentrations by using the VeriKine Human **Interferon** Alpha ELISA Kit following the manufacturer's instructions, and concentration-time data were analyzed by nonlinear-mixed effects modeling as implemented in NONMEM.

8. Volume of Central Compartment (Vc) of **Interferon** α-2b [Time Frame: Before first dose, and 1, 2, 4, 6, 8, 12, and 24 hours postinfusion]

   Samples were analyzed for **interferon** α-2b concentrations by using the VeriKine Human **Interferon** Alpha ELISA Kit following the manufacturer's instructions, and concentration-time data were analyzed by nonlinear-mixed effects modeling as implemented in NONMEM.

9. Systemic Clearance (CL) of **Interferon** α-2B [Time Frame: Before first dose, and 1, 2, 4, 6, 8, 12, and 24 hours postinfusion]

   Samples were analyzed for **interferon** α-2b concentrations by using the VeriKine Human **Interferon** Alpha ELISA Kit following the manufacturer's instructions, and concentration-time data were analyzed by nonlinear-mixed effects modeling as implemented in NONMEM.

10. Mean Total PedsQL 4.0 Scores for Child Quality of Life (QoL) Assessments (Stratum A) [Time Frame: Pretherapy; Weeks 2, 4, 8, 12, and 24; and End of therapy at 6 months and 12 months post]

    QoL assessments were completed using Pediatrics Quality of Life Inventory (PedsQL v4.0). Scale range is 0-100 with higher scores reflecting better quality of life. PedsQL 4.0 healthy sample normative mean ± SD for child report = 83.0 ± 14.8.

11. Mean Total PedsQL 4.0 Scores for Child Quality of Life (QoL) Assessments (Stratum B) [Time Frame: Pretherapy; Weeks 2, 4, 8, 12, and 24; and End of therapy at 6 months and 12 months post]

    QoL assessments were completed using Pediatrics Quality of Life Inventory (PedsQL v4.0). Scale range is 0-100 with higher scores reflecting better quality of life. PedsQL 4.0 healthy sample normative mean ± SD for child report = 83.0 ± 14.8.

12. Mean Total PedsQL 4.0 Scores for Parent Quality of Life Assessments (Stratum A) [Time Frame: Pretherapy; Weeks 2, 4, 8, 12, and 24; and End of therapy at 6 months and 12 months post]

    QoL assessments were completed using Pediatrics Quality of Live Inventory (PedsQL v4.0). Scale range is 0-100 with higher scores reflecting better quality of life. PedsQL 4.0 healthy sample normative mean ± SD for parent report = 87.6 ± 12.3.

13. Mean Total PedsQL 4.0 Scores for Parent Quality of Life Assessments (Stratum B) [Time Frame: Pretherapy; Weeks 2, 4, 8, 12, and 24; and End of therapy at 6 months and 12 months post]

    QoL assessments were completed using Pediatrics Quality of Live Inventory (PedsQL v4.0). Scale range is 0-100 with higher scores reflecting better quality of life. PedsQL 4.0 healthy sample normative mean ± SD for parent report = 87.6 ± 12.3.

14. Mean Total PedsQL 3.0 Scores for Child Cancer Quality of Life (QoL) Assessments (Stratum A) [Time Frame: Weeks 2, 4, 8, 12, and 24; and End of therapy at 6 months and 12 months post]

    QoL assessments were completed using Pediatrics Cancer Quality of Life Inventory (PedsQL v3.0). Scale range is 0-100 with higher scores reflecting better quality of life.

15. Mean Total PedsQL 3.0 Scores for Child Cancer Quality of Life (QoL) Assessments (Stratum B) [Time Frame: Weeks 2, 4, 8, 12, and 24; and End of therapy at 6 months and 12 months post]

    QoL assessments were completed using Pediatrics Cancer Quality of Life Inventory (PedsQL v3.0). Scale range is 0-100 with higher scores reflecting better quality of life.

16. Mean Total PedsQL 3.0 Scores for Parent Cancer Quality of Life (QoL) Assessments (Stratum A) [Time Frame: Weeks 2, 4, 8, 12, and 24; and End of therapy at 6 months and 12 months post]

    QoL assessments were completed using Pediatrics Cancer Quality of Life Inventory (PedsQL v3.0). Scale range is 0-100 with higher scores reflecting better quality of life.

17. Mean Total PedsQL 3.0 Scores for Parent Cancer Quality of Life (QoL) Assessments (Stratum B) [Time Frame: Weeks 2, 4, 8, 12, and 24; and End of therapy at 6 months and 12 months post]

    QoL assessments were completed using Pediatrics Cancer Quality of Life Inventory (PedsQL v3.0). Scale range is 0-100 with higher scores reflecting better quality of life.

18. BASC-2 Psychological Assessment (Stratum A) [Time Frame: Pretherapy, Week 4, Week 24, End of Therapy, and 6 Months Post End of Therapy]

    The Behavioral Assessment System for Children, 2nd Edition (BASC-2) was administered to parents, assessing for any effects on behavior or mood in children undergoing study therapy. The behavior system index (BSI) T-score (range 0-100) is reported for the BASC-2 assessment. Higher scores reflect greater behavioral problems.

19. BASC-2 Psychological Assessment (Stratum B) [Time Frame: Pretherapy, Week 4, Week 24, End of Therapy, and 6 Months Post End of Therapy]

    The Behavioral Assessment System for Children, 2nd Edition (BASC-2) was administered to parents, assessing for any effects on behavior or mood in children undergoing study therapy. The behavior system index (BSI) T-score (range 0-100) is reported for the BASC-2 assessment. Higher scores reflect greater behavioral problems.

20. BRIEF Psychological Assessment (Stratum A) [Time Frame: Pretherapy, Week 4, Week 24, End of Therapy, and 6 Months Post End of Therapy]

    The Behavioral Rating Inventory of Executive Function (BRIEF) was administered to parents, assessing for any effects on behavior or mood in children undergoing study therapy. The global executive composite (GEC) T-score (range 0-100) is reported for the BRIEF assessment. Higher scores reflect poorer executive function.

21. BRIEF Psychological Assessment (Stratum B) [Time Frame: Pretherapy, Week 4, Week 24, End of Therapy, and 6 Months Post End of Therapy]

    The Behavioral Rating Inventory of Executive Function (BRIEF) was administered to parents, assessing for any effects on behavior or mood in children undergoing study therapy. The global executive composite (GEC) T-score (range 0-100) is reported for the BRIEF assessment. Higher scores reflect poorer executive function.

Eligibility Criteria

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Ages Eligible for Study:	up to 21 Years (Child, Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- AJCC stage IIC, III, IV or recurrent cutaneous melanoma
- Adequate bone marrow function

- Age less than or equal to 21 years of age at diagnosis
- Adequate liver and kidney function

Exclusion Criteria:

- Prior Therapy with dacarbazine or temozolomide
- Patients who have uncontrolled infection
- Patients with autoimmune hepatitis
- Patients who have a history of depression or other psychiatric diseases requiring hospitalization
- Patients taking systemic corticosteroids including oral steroids (i.e. prednisone, dexamethasone) or topical steroid creams/ointments. Steroid containing inhalers, steroid replacement for adrenal insufficiency and steroid premedication for prevention of transfusion or imaging contrast-agent related allergic reaction will be permitted.
- Patients with hypersensitivity reaction to non-pegylated interferon α-2b are not eligible for study
- Patients with diabetes mellitus not adequately controlled with medication
- Patients with hypo- or hyperthyroidism not adequately controlled with medication.
- Patients with a history of myocardial infarction, severe or unstable angina, or severe peripheral vascular disease.

Contacts and Locations   Go to ▼

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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): **NCT00539591***

Locations

United States, California

Rady Children's Hospital
San Diego, California, United States, 92123

United States, Tennessee

St. Jude Children's Research Hospital
Memphis, Tennessee, United States, 38105

United States, Texas

The Children's Cancer Hospital at UT M.D. Anderson Cancer Center
Houston, Texas, United States, 77030

Sponsors and Collaborators

St. Jude Children's Research Hospital

Schering-Plough

Investigators

Principal Investigator: Alberto Pappo, MD   St. Jude Children's Research Hospital

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Additional Information:

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Clinical Trials Open at St. Jude   <kbd>EXIT</kbd>

Responsible Party:	St. Jude Children's Research Hospital
ClinicalTrials.gov Identifier:	NCT00539591 History of Changes
Other Study ID Numbers:	MEL06
	NCI-2011-01192 (Registry Identifier: NCI Clinical Trials Registration Program ID)
First Posted:	October 4, 2007 Key Record Dates
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Keywords provided by St. Jude Children's Research Hospital:

Cutaneous **Melanoma**

Additional relevant MeSH terms:

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