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A Novel Treatment for Metastatic Melanoma

This study is currently recruiting participants.

Verified by Northwestern University, February 2010

First Received: June 23, 2008 Last Updated: February 12, 2010 [History of Changes](#)

Sponsor:	Northwestern University
Information provided by:	Northwestern University
ClinicalTrials.gov Identifier:	NCT00758797

▶ Purpose

A novel treatment for metastatic melanoma combining a laser and an immune-system stimulating cream.

Condition	Intervention	Phase
Metastatic Melanoma	Other: Photoimmunotherapy	Phase I

Study Type: Interventional

Study Design: Treatment, Non-Randomized, Open Label, Uncontrolled, Single Group Assignment, Safety/Efficacy Study

Official Title: In Situ Photoimmunotherapy: A Tumor Directed Treatment for Advanced Melanoma With Cutaneous Metastases

Resource links provided by NLM:

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

[U.S. FDA Resources](#)

Further study details as provided by Northwestern University:

Primary Outcome Measures:

- Tolerability, safety, toxicity, of novel treatment through evaluation of subject response and physician observation of adverse events. [Time Frame: 24 weeks]
[Designated as safety issue: Yes]

Secondary Outcome Measures:

- Assess time to disease progression [Time Frame: 24 weeks to years]
[Designated as safety issue: No]
- Evaluate tumor response by measuring clinically apparent tumors throughout study. [Time Frame: 24 weeks] [Designated as safety issue: No]
- Quantify overall survival in this study population [Time Frame: years]
[Designated as safety issue: No]

Estimated Enrollment: 15
 Study Start Date: April 2008
 Estimated Study Completion Date: April 2010
 Estimated Primary Completion Date: April 2010 (Final data collection date for primary outcome measure)

<u>Arms</u>	<u>Assigned Interventions</u>
1: Experimental DIOMED laser + photosensitizing agent injected intralesionally and topical immuno-modulating cream	Other: Photoimmunotherapy DIOMED laser + photosensitizing agent injected intralesionally and topical immuno-modulating cream

Detailed Description:

A novel treatment for metastatic melanoma combining a laser and an immune-system stimulating cream with or without injection of a substance that makes the tumor more sensitive to the laser.

► Eligibility

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

Criteria

Inclusion Criteria:

1. Age 18 and older
2. Subjects must have histologically confirmed cutaneous metastatic malignant melanoma from any tumor site.
3. Patients must have measurable disease. See section 8.2 for the evaluation of measurable disease (RECIST)
4. Eastern Cooperative Oncology Group (ECOG) performance status 0-2
5. Required laboratory parameters (all blood tests must be obtained within 14 days prior to the start of the study treatment):

Platelet count > 40,000 per mm³

Exclusion Criteria:

1. Life expectancy, in the opinion of the investigator of less than 4 months
2. Known allergy to any drugs used in treatment
3. Immunosuppression, including HIV positive subjects, use of systemic steroids daily or other immunosuppressive medications within 1 month of treatment
4. Chemotherapy/immunotherapy within 4 weeks of initiation
5. Local chemotherapy or immunotherapy to target lesions with 4 weeks of initiation
6. Radiation therapy at the treatment site within 4 weeks of initiation
7. Uncontrolled brain metastases
8. History of cutaneous photosensitization or photodermatoses
9. Non-treated, active cancers other than melanoma and non-melanoma skin cancers.
10. Active infectious disease requiring antibiotic therapy
11. Unstable medical illness
12. Past or present major psychiatric illness
13. Pregnant or lactating women

► Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00758797

Contacts

Contact: Marcy Urbanich 312-695-6829 m-urbanich@northwestern.edu
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Locations

United States, Illinois

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Principal Investigator: Murad Alam, MD
Sub-Investigator: Timothy Kuzel, MD
Sub-Investigator: Mary Martini, MD
Sub-Investigator: Jeffrey Wayne, MD
Sub-Investigator: Simon S. Yoo, MD
Sub-Investigator: Misbah Khan, MD
Sub-Investigator: Stephanie A St. Pierre, MD

Sponsors and Collaborators

Northwestern University

Investigators

Principal Investigator: Murad Alam, MD Northwestern University

▶ More Information

No publications provided

Responsible Party: Northwestern University (Murad Alam, MD)
Study ID Numbers: MA-071008
Study First Received: June 23, 2008
Last Updated: February 12, 2010
ClinicalTrials.gov Identifier: [NCT00758797](https://clinicaltrials.gov/ct2/show/study/NCT00758797) [History of Changes](#)
Health Authority: United States: Institutional Review Board

Keywords provided by Northwestern University:
metastatic melanoma

Additional relevant MeSH terms:

Neuroectodermal Tumors	Neoplasms, Nerve Tissue
Neoplasms	Nevi and Melanomas
Neoplasms by Histologic Type	Neuroendocrine Tumors
Neoplasms, Germ Cell and Embryonal	Melanoma

ClinicalTrials.gov processed this record on February 28, 2010

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