Photodynamic Therapy Using Silicon Phthalocyanine 4 in Treating Patients With Actinic Keratosis, Bowen's Disease, Skin Cancer, or Stage I or Stage II Mycosis Fungoides

This study has been completed.

Sponsor:
Case Comprehensive Cancer Center

Collaborator:
National Cancer Institute (NCI)

Information provided by:
Case Comprehensive Cancer Center

ClinicalTrials.gov Identifier:
NCT00103246

First received: February 7, 2005
Last updated: January 19, 2011
Last verified: January 2011
History of Changes

Purpose

RATIONALE: Photodynamic therapy uses a drug that becomes active when it is exposed to a certain kind of light. When the drug is active, tumor cells are killed. Photodynamic therapy using silicon phthalocyanine 4 may be effective against skin cancer.

PURPOSE: This phase I trial is studying the side effects and best dose of photodynamic therapy using silicon phthalocyanine 4 in treating patients with actinic keratosis, Bowen's disease, skin cancer, or stage I or stage II mycosis fungoides.

Condition	Intervention	Phase
Lymphoma Non-melanomatous Skin Cancer Precancerous Condition	Drug: silicon phthalocyanine 4	Phase 1

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

Official Title: Phase I Clinical Trial Using Topical Silicon Phthalocyanine (Pc 4) Photodynamic Therapy (PDT) for the Treatment of Pre-Malignant and Malignant Skin Conditions

Resource links provided by NLM:

Genetics Home Reference related topics: mycosis fungoides Sézary syndrome

MedlinePlus related topics: Cancer Fungal Infections Lymphoma Skin Cancer Skin Conditions

U.S. FDA Resources

Further study details as provided by Case Comprehensive Cancer Center:

Primary Outcome Measures:

- Maximum tolerated dose [Time Frame: Treatment repeats weekly for up to 3 weeks. Cohorts of 3 patients receive escalating doses of Pc 4 and visible light until the maximum tolerated dose (MTD) is determined.] [Designated as safety issue: Yes]
- Local toxicity as measured by physical exam and punch biopsy [Time Frame: at 24 hours and 2 weeks after the start of study treatment] [Designated as safety issue: Yes]
- Treatment efficacy as measured by physical exam and punch biopsy [Time Frame: at 24 hours and 2 weeks after the start of study treatment] [Designated as safety issue: No]
- Systemic photosensitivity as measured by minimum erythema dose (MED) testing [Time Frame: at 2, 24, and 48 hours after completion of

photodynamic therapy] [Designated as safety issue: No]

Enrollment:	43
Study Start Date:	September 2004
Study Completion Date:	August 2010
Primary Completion Date:	December 2008 (Final data collection date for primary outcome measure)

Intervention Details:

Drug: silicon phthalocyanine 4

Patients receive topical silicon phthalocyanine 4 (Pc 4). One hour later, patients undergo photodynamic therapy. Treatment repeats weekly for up to 3 weeks (up to 3 total treatments for the same lesion OR up to 3 lesions treated if multiple lesions are present).Cohorts of 3 patients receive escalating doses of Pc 4 and visible light until the maximum tolerated dose (MTD) is determined.

Other Name: Pc 4

Detailed Description:
OBJECTIVES:

- Determine the maximum tolerated dose of photodynamic therapy using topically delivered silicon phthalocyanine 4 in patients with actinic keratosis, Bowen's disease, squamous cell or basal cell skin cancer, or stage IA, IB, IIA, or IIB mycosis fungoides.
- Determine the safety and toxicity of this therapy with emphasis on whether it induces photosensitivity in non-treated sites in these patients.
- Determine the antitumor mechanism of this therapy, by monitoring tissue changes via clinical, histological, immunohistochemical, and other biochemical markers, in these patients.
- Determine, preliminarily, the dose of this therapy that results in highest clearing rates in these patients.

OUTLINE: This is a dose-escalation study.

Patients receive topical silicon phthalocyanine 4 (Pc 4). One hour later, patients undergo photodynamic therapy. Treatment repeats weekly for up to 3 weeks (up to 3 total treatments for the same lesion OR up to 3 lesions treated if multiple lesions are present).

Cohorts of 3 patients receive escalating doses of Pc 4 and visible light until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose preceding that at which 1 of 3 patients experiences dose-limiting toxicity. Three additional patients are treated at the MTD.

After completion of study therapy, patients are followed for up to 2 weeks.

PROJECTED ACCRUAL: A total of 16-45 patients will be accrued for this study.

Eligibility

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

Criteria

DISEASE CHARACTERISTICS:

- Histologically confirmed diagnosis of 1 of the following:
  - Actinic keratosis
  - Bowen's disease
  - Squamous cell skin cancer
  - Basal cell skin cancer
  - Clinical stage IA, IB, IIA, or IIB mycosis fungoides
- Fitzpatrick skin type I-IV

PATIENT CHARACTERISTICS:

Age

- 18 and over

Performance status

- ECOG 0-2

Life expectancy

- Not specified

Hematopoietic

- Not specified

Hepatic

- Not specified

Renal

- Not specified

Other

- Not pregnant or nursing
- Negative pregnancy test
- Fertile patient must use effective contraception
- No diabetes mellitus
- No known hypersensitivity to ethanol or propylene glycol
- No significant history of photosensitivity, including diagnosis of any of the following:
  - Porphyria
  - Lupus erythematosus
  - Xeroderma pigmentosum
  - Severe polymorphous light eruption
  - Solar urticaria

PRIOR CONCURRENT THERAPY:

Biologic therapy

- Not specified

Chemotherapy

- No concurrent chemotherapy

Endocrine therapy

- Not specified

Radiotherapy

- More than 2 weeks since prior anticancer radiotherapy
- No concurrent radiotherapy

Surgery

- Lesions must be healed after prior biopsy

Other

- More than 2 weeks since prior topical, local, or systemic anticancer therapy
- More than 2 weeks since prior anticancer phototherapy
- More than 2 weeks since prior photosensitizing medications, including any of the following:

- Tetracyclines
- Quinolones
- Psoralens
- Hydrochlorothiazide
- Furosemide
- Trimethoprim-sulfamethoxazole
- Griseofulvin
- Nalidixic acid
- Amiodarone
- Phenothiazines
- High-dose nonsteroidal anti-inflammatory drugs

- No other concurrent photosensitizing medications
- No concurrent therapeutic dose of warfarin that may cause excessive bleeding during skin biopsy

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00103246

Locations

United States, Ohio

Case Medical Center, University Hospitals Seidman Cancer Center, Case Comprehensive Cancer Center
Cleveland, Ohio, United States, 44106-5065

Sponsors and Collaborators

Case Comprehensive Cancer Center

National Cancer Institute (NCI)

Investigators

Principal Investigator: Kevin Cooper, MD Case Medical Center, University Hospitals Seidman Cancer Center, Case Comprehensive Cancer Center

Principal Investigator: Elma Baron, MD Case Medical Center, University Hospitals Seidman Cancer Center, Case Comprehensive Cancer Center

More Information

Additional Information:

Clinical trial summary from the National Cancer Institute's PDQ® database EXIT

No publications provided

Responsible Party:	Elma D. Baron, MD, Case Medical Center, University Hospitals Seidman Cancer Center, Case Comprehensive Cancer Center
ClinicalTrials.gov Identifier:	NCT00103246 History of Changes
Other Study ID Numbers:	CASE1Y04, P30CA043703, CASE-CWRU-1Y04, 10-03-01, CASE1Y04
Study First Received:	February 7, 2005
Last Updated:	January 19, 2011
Health Authority:	United States: Federal Government United States: Food and Drug Administration

Keywords provided by Case Comprehensive Cancer Center:

skin cancer
squamous cell carcinoma of the skin
basal cell carcinoma of the skin
recurrent skin cancer
recurrent mycosis fungoides/Sezary syndrome
stage I mycosis fungoides/Sezary syndrome
stage II mycosis fungoides/Sezary syndrome
actinic keratosis
recurrent cutaneous T-cell non-Hodgkin lymphoma
stage I cutaneous T-cell non-Hodgkin lymphoma
stage II cutaneous T-cell non-Hodgkin lymphoma

Additional relevant MeSH terms:

Skin Neoplasms
Keratosis
Keratosis, Actinic
Lymphoma
Mycosis Fungoides
Precancerous Conditions
Neoplasms by Site
Lymphoma, T-Cell
Lymphoma, Non-Hodgkin
Silicon
Phthalocyanine
Silicon phthalocyanine
Trace Elements
Micronutrients

Neoplasms
Skin Diseases
Neoplasms by Histologic Type
Lymphoproliferative Disorders
Lymphatic Diseases
Immunoproliferative Disorders
Immune System Diseases
Lymphoma, T-Cell, Cutaneous

Growth Substances
Physiological Effects of Drugs
Pharmacologic Actions
Radiation-Sensitizing Agents
Antimalarials
Antiprotozoal Agents
Antiparasitic Agents
Anti-Infective Agents

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