Silicon Phthalocyanine 4 and Photodynamic Therapy in Stage IA-IIA Cutaneous T-Cell Non-Hodgkin Lymphoma

This study is currently recruiting participants.

Verified April 2013 by Case Comprehensive Cancer Center

Sponsor:
Kevin Cooper MD

Collaborator:
National Cancer Institute (NCI)

Information provided by (Responsible Party):
Kevin Cooper MD, Case Comprehensive Cancer Center

ClinicalTrials.gov Identifier:
NCT01800838

First received: February 26, 2013
Last updated: April 15, 2013
Last verified: April 2013
History of Changes

Purpose

This phase I trial studies the side effects and best dose of silicon phthalocyanine 4 and photodynamic therapy in treating patients with stage IA-IIA cutaneous T-cell non-Hodgkin lymphoma. Photodynamic therapy (PDT) uses a drug, silicon phthalocyanine 4, that becomes active when it is exposed to a certain kind of light. When the drug is active, cancer cells are killed. This may be effective against cutaneous T-cell non-Hodgkin

lymphoma

Condition	Intervention	Phase
Recurrent Cutaneous T-cell Non-Hodgkin Lymphoma Recurrent Mycosis Fungoides/Sezary Syndrome Stage I Cutaneous T-cell Non-Hodgkin Lymphoma Stage IA Mycosis Fungoides/Sezary Syndrome Stage IB Mycosis Fungoides/Sezary Syndrome Stage II Cutaneous T-cell Non-Hodgkin Lymphoma Stage IIA Mycosis Fungoides/Sezary Syndrome	Drug: silicon phthalocyanine 4 Drug: photodynamic therapy Other: pharmacological study Other: laboratory biomarker analysis	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: Silicon Phthalocyanine Pc4 for Photodynamic Therapy of Cutaneous T-cell Lymphoma: Single and Repeated Photoexposures

Resource links provided by NLM:

Genetics Home Reference related topics: mycosis fungoides Sézary syndrome

MedlinePlus related topics: Cancer Fungal Infections Lymphoma

U.S. FDA Resources

Further study details as provided by Case Comprehensive Cancer Center:

Primary Outcome Measures:

- MTD defined as the dose immediately below the dose in which 2 or more of 6 patients experience a grade 4 toxicity assessed using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.0 [Time Frame: Up to 30 days]
  [Designated as safety issue: Yes]

Estimated Enrollment:	24
Study Start Date:	April 2013
Estimated Primary Completion Date:	August 2014 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Treatment (silicon phthalocyanine 4 and PDT) Patients receive silicon phthalocyanine 4 topically and then undergo PDT.	Drug: silicon phthalocyanine 4 Given topically Other Names: • Pc 4 • Pc-4 (Silicone phthalocyanine) Drug: photodynamic therapy Undergo DPT Other Names: • Light Infusion Therapy™ • PDT • therapy, photodynamic Other: pharmacological study Correlative studies Other Name: pharmacological studies Other: laboratory biomarker analysis Correlative studies

Detailed Description:
PRIMARY OBJECTIVES:

I. Determine the safety and maximum tolerated dose (MTD) that can be utilized for a single treatment of Pc 4-PDT (silicon phthalocyanine 4 photo dynamic therapy) on subjects with mycosis fungoides (MF)/cutaneous T-cell lymphoma (CTCL) stage IA-IIA, by evaluating an accelerated dose escalation protocol consisting of a single exposure to PDT using topically-applied Pc 4 and visible light at a wavelength of 675 nm, followed by assessment of skin biopsies to analyze cellular and molecular changes induced by Pc 4-PDT. (Cohort I)

II. Determine safety and tolerability of repeated light (PDT) exposures after a single application of Pc 4 to a MF/CTCL plaque, using topically-applied Pc 4 and visible light at a wavelength of 675nm, followed by assessment of skin biopsies to analyze cellular and molecular changes induced by Pc 4-PDT. (Cohort II)

III. Identification of targets for assessment of efficacy to assist in planning for a Phase II study.

OUTLINE: This is a dose-escalation study.

Patients receive silicon phthalocyanine 4 topically and then undergo PDT.

After completion of study treatment, patients are followed up at 24 hours, 1 week, 2 weeks, and 30 days.

Eligibility

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

Criteria

Inclusion Criteria:

- Diagnosed with early stage MF (CTCL stage IA-IIA)
- Has at least 2 evaluable plaques
- Has been off systemic therapies for at least 4 weeks
- Has been off topical therapies for at least 2 weeks
- Has been off phototherapies for at least 2 weeks
- All skin photo-types will be included
- Subjects must have the ability to understand and the willingness to sign a written informed consent form
- Women of child-bearing potential must agree to utilize a birth control which results in a failure rate of less that 1% per year during the study; accepted forms of birth control for this study include: injections such as Depo-Provera and Lunelle, implants such as Norplant, and intra-uterine devices
- Sexually active males must agree to use a medically acceptable form of birth control for the duration of the study and for at least 3 months after the last dose of the study medication; appropriate birth control methods are using a condom with a spermicide or surgical sterilization

Exclusion Criteria:

- Active history of photosensitivity (e.g. xeroderma pigmentosum, lupus erythematosus, porphyria, severe polymorphous light eruption, solar

urticaria)

- Any medical condition that could be aggravated or may cause extreme discomfort during the study period
- Lesions only on the face, scalp or other sites that would make biopsies not cosmetically acceptable
- Women of childbearing potential who are pregnant or attempting to become pregnant are excluded from this study
- History of allergic reactions attributed to compounds of similar chemical or biologic composition to silicon phthalocyanine (Pc 4) or other agents used in this study
- Patients with uncontrolled intercurrent illness including, but not limited to ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01800838

Locations

United States, Ohio

Case Medical Center, University Hospitals Seidman Cancer Center, Case Comprehensive Cancer Center — **Recruiting**
Cleveland, Ohio, United States, 44106
Contact: Elma D. Baron, MD 800-641-2422 elma.baron@case.edu
Principal Investigator: Elma D. Baron

Sponsors and Collaborators

Kevin Cooper MD

National Cancer Institute (NCI)

Investigators

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

More Information

No publications provided

Responsible Party:	Kevin Cooper MD, Department Chairman, Dermatology, Case Comprehensive Cancer Center
ClinicalTrials.gov Identifier:	NCT01800838 History of Changes
Other Study ID Numbers:	CASE2411, NCI-2013-00089
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Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Lymphoma
Lymphoma, Non-Hodgkin
Mycoses
Mycosis Fungoides
Sezary Syndrome
Lymphoma, T-Cell
Lymphoma, T-Cell, Cutaneous
Neoplasms by Histologic Type
Neoplasms
Lymphoproliferative Disorders
Lymphatic Diseases
Immunoproliferative Disorders
Immune System Diseases
Silicon
Phthalocyanine
Silicon phthalocyanine
Trace Elements
Micronutrients
Growth Substances
Physiological Effects of Drugs
Pharmacologic Actions
Radiation-Sensitizing Agents
Antimalarials
Antiprotozoal Agents
Antiparasitic Agents
Anti-Infective Agents
Therapeutic Uses
Antiviral Agents
Photosensitizing Agents
Dermatologic Agents

ClinicalTrials.gov processed this record on April 29, 2013

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