Penn Medicine

CLINICAL BRIEFING™

Department of Radiation Oncology • Mesothelioma and Pleural Program

Enrolling Clinical Trials: Photodynamic Therapy (PDT) for the Treatment of Pleural Mesothelioma and Pleural Malignancies

Researchers at Penn Medicine are investigating the addition of photodynamic therapy (PDT) to lung-sparing radical pleurectomy and post-operative chemotherapy for the treatment of mesothelioma and pleural malignancies.

The components of PDT are surprisingly modest: a photosensitizer and a light source of a wavelength sufficient to initiate a reaction in the agent. Injected prior to the procedure, the sensitizer accumulates selectively in tumor cells for 24 to 48 hours, at which time they are exposed to the light source (typically a laser). The light provokes the generation of an active form of oxygen within the cancer cells, leading to tumor necrosis, DNA fragmentation and membrane damage.

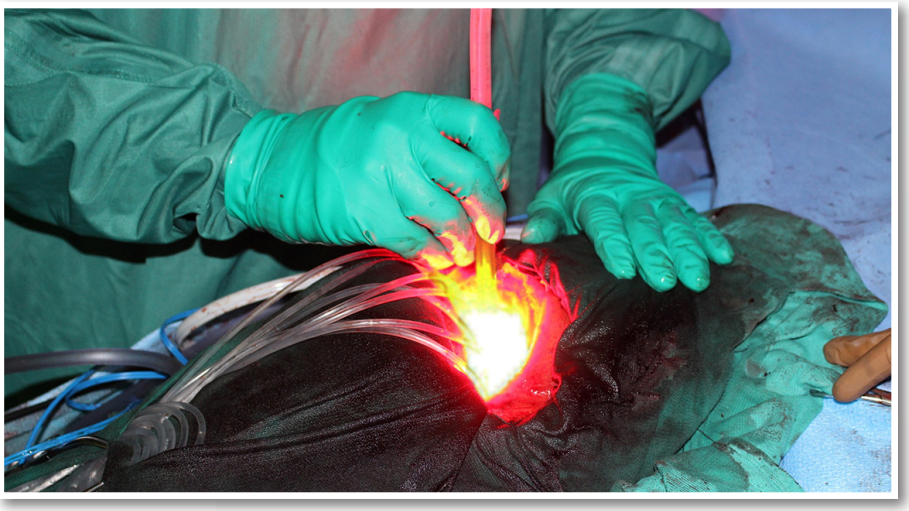

Figure 1: Intraoperative photodynamic therapy (PTD) combines a light source of a specific wave-length with a photosynsitizing agent to produce an active form of oxygen that provokes DNA fragmentation and membrane damage in tumor cells.

Researchers at Penn Medicine have pioneered the use of a lung-sparing surgery to treatment malignant pleural mesothelioma and have demonstrated that this surgery improves patient quality of life and improves overall survival compared with surgery that removes the entire lung. These investigators have recently initiated an NIH-supported clinical trial to investigate PDT in combination with radical pleurectomy for the treatment of malignant pleural mesothelioma (MPM). PDT has been an established therapy at Penn Medicine since 1996, and this study will complement ongoing treatment protocols for disseminated cancers of the thoracic cavities and early-stage diseases such as head and neck cancers and anal cancer.

The investigation focuses on the effects of intraoperative PDT on tumors, the surrounding normal tissues, the immune system, and clinical outcomes of patients with MPM.

MPM PDT Phase II Trial

ClinicalTrials.gov Identifier: NCT02153229

Summary: A Phase II randomized study to test whether the addition of photofrin-mediated intra-operative photodynamic therapy (PDT) to radical pleurectomy and post-operative chemotherapy improves overall survival in the treatment of patients with epithelioid MPM, the most common form of the disease.

All patients will have radical pleurectomy with the goal of achieving a macroscopic complete resection followed by four cycles of post-operative chemotherapy, and they will then be randomized to receive radical pleurectomy with or without intra-operative PDT, followed by chemotherapy. Patients assigned to the PDT arm will be given the photosensitizer prior to surgery and will receive intraoperative light treatment using novel, real-time, isotropic light dosimetry. Patients assigned to the radical pleurectomy arm will receive chemotherapy alone after surgery, without PDT.

For information about this trial, please contact Sally McNulty, RN, at 215-662-7720 or Keith Cengel, MD, PhD, at 855-216-0098, or write PennCancerTrials@emergingmed.com

The PDT Program is also performing a prospective outcomes study of all patients who have received PTD therapy for neoplastic diseases at Penn.

Prospective Follow-up of Outcomes in Patients Receiving Photodynamic Therapy for Neoplastic Diseases

ClinicalTrials.gov Identifier: NCT02159742

Summary: This is a prospective study of all patients with malignant pleural mesothelioma or other malignancies with pleural dissemination who are being treated with definitive surgical resection and intraoperative photodynamic therapy (PDT). The study will review treatment parameters (including surgical procedure and photodynamic therapy administration) and treatment outcomes for all organ functions, performance status, tumor recurrence, laboratory values and any other data present in the routinely documented follow-up visits.

Following de-identification, all data will be added to the existing PDT treatment outcome databases for outcomes analysis, quality improvement and reporting of results in abstract and manuscript forms.

For information about this trial, please contact contact Ashley Feriozzi, BS, at 215-615-3272 or Charles Simone, MD, at 855-216-0098 or write PennCancerTrials@emergingmed.com.

FACULTY TEAM

The Penn Mesothelioma and Pleural Program is comprised of multi-disciplinary investigators across radiation oncology, medical oncology, surgery, pulmonology, radiology, pathology, immunology, radiation biology, and medical physics. Their innovative and practice-changing research has led to numerous clinical advances and research funding.

Performing Clinical Studies in PTD for Mesothelioma and Pleural Disease at Penn Medicine

Evan W. Alley, MD, PhD
Chief, Division of Hematology and Medical Oncology
Co-Director, Penn Mesothelioma and Pleural Program
Penn Presbyterian Medical Center

Keith Cengel, MD, PhD
Associate Professor of Radiation Oncology
Director, Photodynamic Therapy Program

Charles B. Simone, II, MD
Co-Director, Penn Mesothelioma and Pleural Program
Assistant Professor of Radiation Oncology
Chief, Thoracic Oncology Service

ACCESS

Penn Mesothelioma and Pleural Program
Penn Medicine University City
4th Floor
3737 Market Street
Philadelphia, PA 19104

Penn Radiation Oncology
Perelman Center for Advanced Medicine
Concourse Level
3400 Civic Center Boulevard
Philadelphia, PA 19104

Additional Enrolling Mesothelioma Clinical Studies at the Abramson Cancer Center

Safety and Efficacy of Listeria in Combination With Chemotherapy as Front-line Treatment for Malignant Pleural Mesothelioma

ClinicalTrials.gov Identifier: NCT01675765

This clinical trial will evaluate the safety and immune response of the sequential administration of cancer vaccine CRS-207 (with or without cyclophosphamide) followed by standard of care chemotherapy (pemetrexed and cisplatin). CRS-207 is a weakened (attenuated) form of Listeria monocytogenes that has been genetically-modified to reduce its capacity to cause disease, while maintaining its ability to stimulate potent immune responses. CRS-207 has been engineered to elicit an immune response against the tumor-associated antigen mesothelin, which has been shown to be present at higher levels on certain tumor cells (such as mesothelioma) than on normal cells. Pemetrexed and cisplatin are the standard chemotherapy regimen to treat malignant pleural mesothelioma. This trial will evaluate whether giving CRS-207 cancer vaccine with chemotherapy will induce anti-tumor immune responses and/or objective tumor response.

For information about this trial, please contact: Mona Jacobs-Small, B.S., RRT, CCRC at 215- 662-8632 or mona.jacobs-small@uphs.upenn.edu; or write Evan Alley, MD, PhD at evan.alley@uphs.upenn.edu.

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