

BREAST CANCER CLINICAL TRIAL

In situ photoimmunotherapy: a tumor-directed treatment for breast cancer

What is the purpose of the trial?

The trial is designed to evaluate a novel experimental therapy for breast cancer tumors. There is an urgent need to develop more effective cancer therapy. Cancer is the second leading cause of death in the United States, behind only heart disease. Current therapies—including chemotherapy, radiation and surgery—can be ineffective and with significant side effects for the patients.

Our trial combines two proven treatments: laser energy and drugs that enhance the immune system. Working together, these two approaches first weaken the tumor and then stimulate the body to attack and destroy the cancer cells.

What is laser-assisted immunotherapy?

A laser is a focused beam of light energy. Lasers are already used in many branches of medicine, and they are promising new tools in the fight against cancer. In laser therapy, the cancer cells are injected with a special drug called a photosensitizer. In this case, the photosensitizer is called indocyanine green, or IGC. It is injected directly into the tumor, where it remains for up to 48 hours. Shortly after the IGC is injected, the tumor is pulsed with short bursts of laser light. The IGC absorbs the laser energy, causing the cancer cells to heat up. Cancer cells are very vulnerable to changes in temperature, which can kill or weaken them. The kind of laser used in this study is already FDA-approved for a variety of therapies, including cardiovascular, kidney and eye diseases.

This protocol is unique, however, because it combines laser therapy with immunotherapy. Immunotherapy means using the body's own system to attack and kill invader cells. Vaccines and allergy shots are forms of immunotherapy. Traditionally, immunotherapy has only limited effectiveness in cancer treatment because it's hard to target the immune response against cancer cells. Our study uses a substance called glycated chitosan (GC), which is injected at the same time as the IGC. Chitosan is a nontoxic, biodegradable substance that has been shown to stimulate immune responses.

How does chitosan work?

The chitosan begins to work after the laser has weakened and disrupted the tumor cells. It first activates the immune system throughout the body. Over time, the body recognizes the cancer cells as invaders and begins to attack them specifically. It is not an immediate process—the immune system needs time after the laser treatment to mount an attack. In our early clinical studies, the tumors continued to grow for up to 30 days after treatment before they were eliminated.

Why do we think it will work?

This protocol has been tested with very promising results in animals with aggressive breast cancer. In our initial animal studies, we achieved a 50% percent response and a 300% percent increase in survival time. During these experiments, we compared animals with tumors that had been treated with laser/IGC/GC treatment versus ones that were not treated. We found that tumors disappeared about 40 days after treatment, while they continued to grow unchecked in the untreated animals. After 180 days, the treated animals had no evidence of cancer recurrence.

Who is eligible for the study?

The study is open to patients with recurrent breast cancer. Both men and women are eligible, as long as they meet the following criteria:

- You are between 20 and 80 years of age
- You have no other therapeutic options available
- You can make all your appointments for the duration of the study
- You are free of any systemic diseases that would complicate the study
- You are not taking any other drugs or therapies (i.e., cytokine therapy or steroid treatment)
- You are not already in treatment for cancer (except for maintenance therapy)
- You do not have Class III or Class IV heart failure or poorly controlled diabetes
- You are not depressed or suicidal

Patients are free to withdraw from the study at any point. Investigators are also free to withdraw patients from the study. We are hoping to enroll 50 patients. All enrolled patients will receive the treatment.

How long will the study last?

The study is expected to run for one year. During that time, patients will receive the laser/IGC/GC treatment and multiple examinations, including blood work, physical exams, radiography and other measures. Any side effects or adverse events will be closely monitored throughout the course of the study.

What happens when the study is over?

The study is expected to run for one year, unless it is terminated early. Once it is over, we will carefully analyze the results to see if the treatment was effective. Success is measured by tumor size, lab work, and the safety of the treatment. Patients will be followed up for one year. Study results may be submitted for publication in a professional medical journal.