

Baylor Clinic Healthletter



Focus on Pancreatic Cancer

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By William E. Fisher, MD, FACS, Director, The Elkins Pancreas Center at Baylor College of Medicine

In 2007, an estimated 37,000 people in the U.S. will be diagnosed with pancreatic cancer. The vast majority will not survive. Pancreatic cancer has the highest fatality rate of all cancers and ranks as the number four cancer killer in the U.S. among both men and women. To date, there are no effective early detection methods and standard treatment options have yet to achieve long-term success against this disease. All of which makes it imperative that we continue the research that will one day lead to new breakthroughs in detection, treatment, and ultimately a cure.

There are several known risk factors for pancreatic cancer, including:

- **Age** – Most cases of pancreatic cancer are found in individuals over the age of 60.
- **Gender** – More men than women are diagnosed with pancreatic cancer.
- **Smoking** – Smoking during college has been linked to a two- to three-fold increased risk of pancreatic cancer. Cigarette smoke contains a large number of carcinogens and is a leading cause of many cancers, so it is not surprising that it factors into pancreatic cancer.
- **Diabetes** – A new diagnosis of diabetes or a case of diabetes that continues to worsen in older patients is a potential sign of pancreatic cancer.
- **Race** – Studies in the U.S. have shown that pancreatic cancer is more common in the African-American population than in the white population.
- **Family history** – The risk of developing pancreatic cancer triples if a parent or sibling had the disease.
- **Chronic pancreatitis** – Chronic pancreatitis, particularly inherited chronic pancreatitis, increases the risk of later developing pancreatic cancer.

Possible signs and symptoms of pancreatic tumors include:

- Jaundice (yellowing of skin and the whites of the eyes)
- Pain in the upper or middle abdomen, sometimes radiating to the back
- Unexplained weight loss
- Loss of appetite
- Fatigue
- Nausea and vomiting
- Severe itching

Because the symptoms of pancreatic cancer are vague at first, in many cases a diagnosis is not made until the patient has jaundice and weight loss.

Patients diagnosed with pancreatic cancer frequently have either locally advanced disease, meaning the cancer has spread to nearby tissues, or metastatic disease, meaning it has spread to other organs of the body. Patients with locally advanced disease are often treated with chemotherapy and sometimes radiation, but the tumors rarely respond. Cases where the tumor is successfully reduced in size and resected, or surgically removed, are uncommon.

Approximately 15 percent of patients with pancreatic cancer are diagnosed at a time when the disease is still confined to the pancreas. These patients are usually treated with a surgical procedure known as pancreaticoduodenectomy or a “Whipple” procedure. This is a major operation in which the head of the pancreas is removed, along with the duodenum, distal bile duct and gallbladder.

Most patients are found to have cancer that has spread to the lymph nodes. Once the tumor is removed, the standard of care is chemotherapy, usually combined with radiation treatment. Despite this aggressive approach, most patients suffer a recurrence of their disease and survive only about two years after successful surgery.

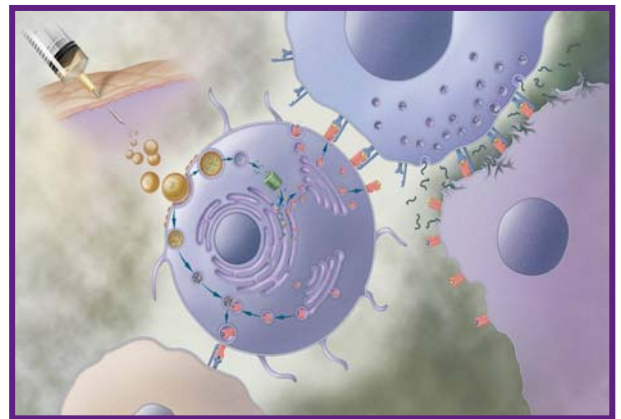
At The Elkins Pancreas Center, a team of Baylor College of Medicine doctors work together to develop the best individualized treatment plan for patients with pancreatic cancer. This team includes surgical, medical, and radiation oncologists, gastroenterologists, radiologists, and pathologists, all collaborating to deliver coordinated, personalized care.

Clinical Trials

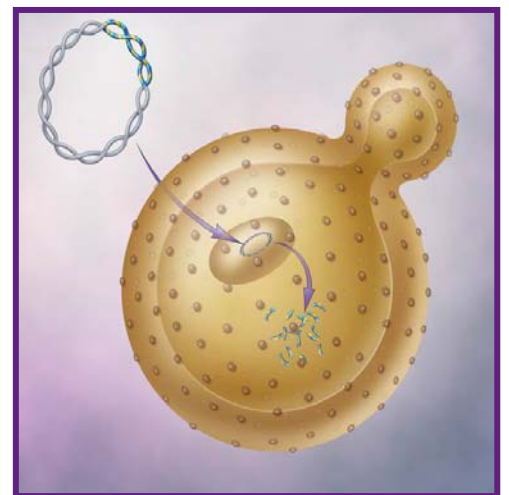
Because of the lack of effective treatment options today, experts in the field of pancreatic cancer agree that the most appropriate recommendation for patients is to be offered participation in a clinical trial, where promising new treatments are studied. In an effort to find a cure, The Elkins Pancreas Center has a clinical trial for patients at every stage of this terrible disease. Our goal: to offer patients hope by providing *“tomorrow’s treatment today through research.”*

Clinical trials available at The Elkins Pancreas Center include:

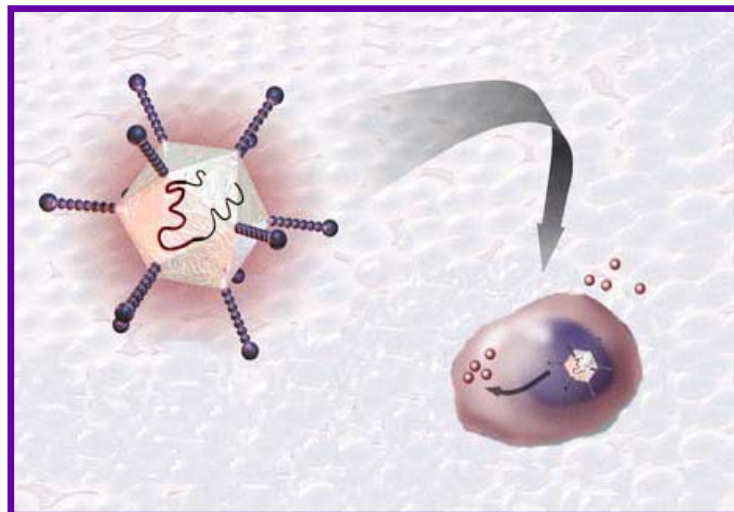
- **Adjuvant Immunotherapy for Resectable Disease -**
This trial involves immunotherapy, or stimulation of the patient’s immune system to attack the tumor cells. Patients are administered weekly doses of a study drug designed to trigger the body to kill targeted diseased cells found in more than 80-90 percent of pancreatic cancers. These targeted therapies are called Tarmogens (from Targeted Molecular Immunogens). The study compares immunotherapy versus placebo; both groups receive standard of care postoperative chemotherapy.



In this study, the DNA from the patient’s tumor is sequenced after surgery to determine eligibility. Patients with tumors positive for the targeted disease cells, known as K-Ras gene mutations, and with successful tumor resections will be eligible for participation in the study. Patients begin immunotherapy (or placebo) three to five weeks following surgery and receive regular doses of the study drug prior to and in between chemotherapy cycles. The primary objective of the study is to measure the recurrence-free survival of patients 15 months after surgery. The study also measures overall survival, symptoms, the presence of antigen specific T-cell responses (or how much the immune system is stimulated to fight the cancer), and safety of the immunotherapy when combined with the chemotherapy medication.



- Neoadjuvant Gene Therapy for Locally Advanced Disease** - This study compares the standard of care treatment of chemotherapy and radiation to a novel therapy using a biologic agent known as TNFerade™ in addition to the standard therapy. TNFerade therapy stimulates the production of a naturally occurring protein that promotes tumor cell death. TNFerade is injected directly into the tumor. Some patients who received TNFerade had their tumors decrease in size, making them eligible for surgery. While the trial is still enrolling new patients and assessment of the response is ongoing, an interim analysis of safety and effectiveness after the first 51 patients showed the treatment was well tolerated. One-year survival, the primary objective of the study, was 70.5 percent with TNFerade versus 28.0 percent with standard treatment. The median survival for TNFerade patients was 515 days compared to 335 days for patients receiving standard treatment.



- Immunotherapy for Locally Advanced or Metastatic Disease** - For patients with this stage of pancreatic cancer, a vaccine known as the peptide vaccine GV1001 has been developed to activate and stimulate the body's immune system (in particular the T-cells) to identify and kill cancer cells. The purpose of this study is to investigate the effectiveness of GV1001 in combination with gemcitabine, a chemotherapy drug, in locally advanced or metastatic pancreatic cancer. Patients are randomly selected to receive gemcitabine or immunotherapy. Gemcitabine is added to the immunotherapy once the clinical trial is underway.

Why should patients with pancreatic cancer be offered a clinical trial?

There are many advantages to participating in a clinical trial, including the opportunity to receive healthcare from leading physicians in the field of pancreatic cancer research. Patients in a clinical trial also gain access to new drugs and interventions like gene therapy before they are widely available. If the approach being studied is found to be helpful, they may be among the first to benefit. In addition, patients in clinical trials benefit from intense follow up and attention to detail required for clinical research. They also take a more active role in their own healthcare.

Participation in a clinical trial offers an opportunity to make a valuable contribution to pancreatic cancer research and possibly help find a cure. Many cases of breast cancer, Hodgkin's Lymphoma, prostate cancer, and leukemia are being cured today thanks to those who participated in clinical trials. We are dedicated to achieving these same advances for patients with pancreatic cancer.

For more information on pancreatic cancer or the clinical trials offered at The Elkins Pancreas Center at Baylor College of Medicine, call **1.877.PANC CTR** (1.877.726.2287).

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The Elkins Pancreas Center is dedicated to providing the best care for pancreatic cancer patients in the country, to leading the nation in the discovery of effective new methods to diagnose and treat pancreatic cancer, and to educating patients, their families, our trainees, other physicians, and the community about pancreatic cancer. Our patients benefit from the coordinated care of an extraordinary team of specialists – including gastroenterologists, radiologists, pathologists, and surgical, medical, and radiation oncologists – and from breakthrough research and promising clinical trials that are advancing the treatment of pancreatic cancer.

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www.debakeydepartmentofsurgery.org (Select Patient Care: Clinics & Centers)

