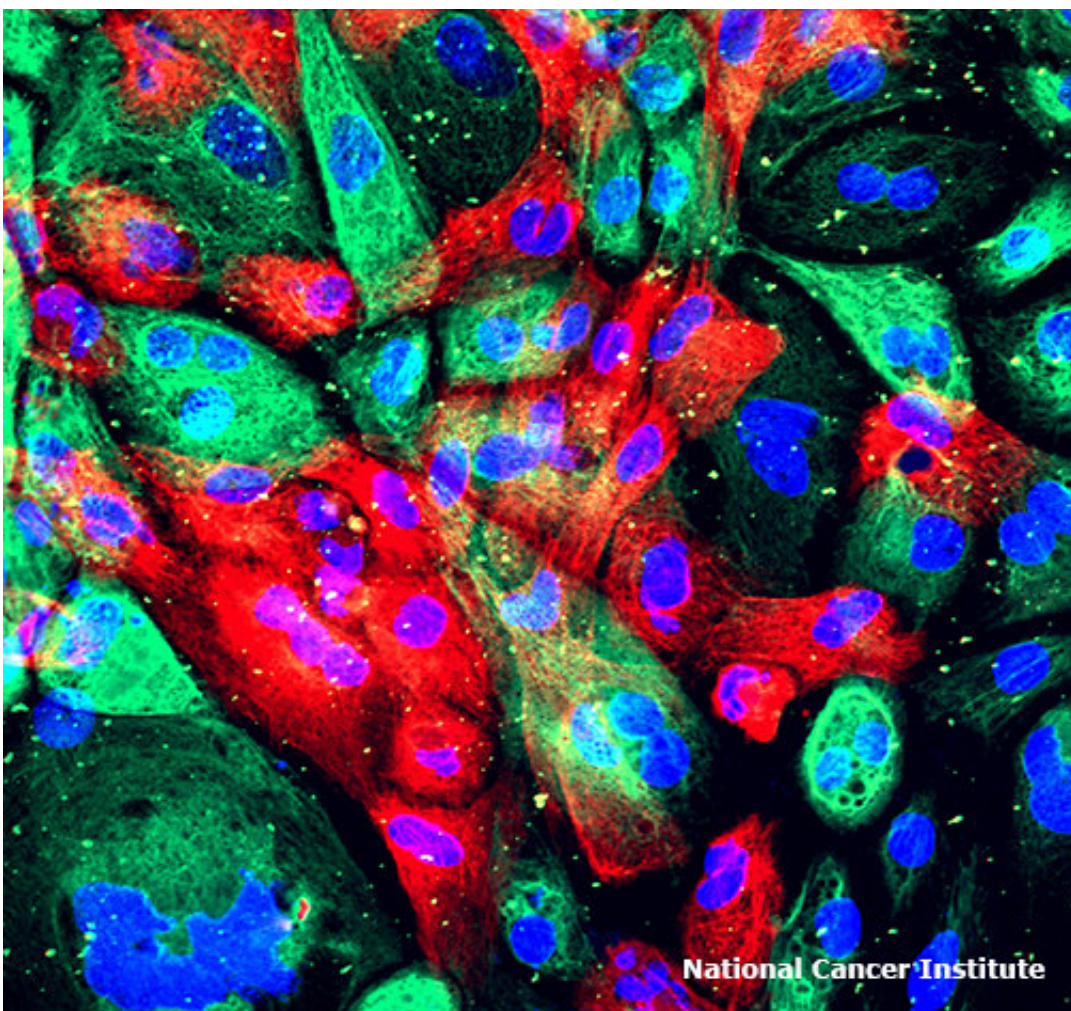


Prostate cancer clinical trial seeking Rx approach answers for survival and quality of life

September 25 2018



Credit: NHI

LSU Health New Orleans Scott Cancer Center has enrolled the first patients in the United States in a National Cancer Institute/Southwest Oncology Group clinical trial for men whose prostate cancer has spread. The Phase III multi-center trial will compare the outcomes of treating men diagnosed with metastatic Stage 4 prostate cancer with standard systemic therapy or with standard systemic therapy in combination with either surgery or radiation therapy.

"The main question being asked is, does treatment of the residual [cancer](#) left within the [prostate](#) affect how long a patient will survive and with good quality of life," says Scott Delacroix, Jr., MD, Director of Urologic Oncology at LSU Health New Orleans School of Medicine and principal investigator of the LSU Health New Orleans study site. "Currently, when a patient presents to the doctor when the cancer has already spread to the bone or other organs, the standard of care is to treat them with medications called 'systemic' therapies, which are carried by the bloodstream to cancer cells wherever they are. Patients with [metastatic prostate cancer](#) are not usually offered therapy targeting the prostate where the cancer originated, and often the bulk of the cancer still remains."

This trial seeks to determine if adding either prostate surgery or radiation therapy to the usual combination of drugs will delay the progression of the disease and result in improved survival.

To qualify, potential participants must have been diagnosed with Stage 4 metastatic prostate cancer within the past 6 months and have not received prior local treatment. The trial is randomized meaning participants will be randomly assigned by computer to one of two groups. Group One participants will receive the current standard of care—the best systemic therapy. Group Two participants will receive the best [systemic therapy](#) with treatment also directed to the prostate through surgery or radiation. The choice of radiation or surgery is up to the

participant and his doctor. More than 1,200 men will be enrolled at centers across North America—636 in each group. All patients will receive treatment throughout the course of their disease.

There are both risks and benefits to taking part in this study. The addition of the surgery or radiation therapy to the usual treatment could help patients live longer, but it could also cause side effects. A smaller Phase 2 trial using the same approach at MD Anderson showed promising results, prompting the NCI and Southwest Oncology Group to expand the trial. The preliminary study found there is evidence that the study approach can be effective in reducing the amount of cancer in the body, but it is not possible to know at this time if the study drugs, surgery or radiation will affect how long participants live compared to men treated with the standard of care. Potential risks include side effects related to local therapy in addition to the standard systemic therapies that are currently in place. These may include impaired function of the liver, kidneys, heart, blood and urinary system. Participants may stop taking part in the study at any time.

This study will determine if this different treatment approach is better, the same, or worse than the usual approach. Results may help improve treatment for people in the future.

According to the National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) Program, the incidence rate of prostate cancer in Louisiana men is higher than the national average. The SEER Program is one of the most authoritative sources of cancer incidence and mortality facts and figures. LSU Health New Orleans' Louisiana Tumor Registry is one of the 16 competitively funded cancer registries that make up the SEER Program, which found that in Louisiana, the rate is 137.4 cases per 100,000 men, while the US incidence rate is 109 per 100,000. In Orleans Parish, the prostate cancer incidence rate is 152.6 per 100,000. The highest prostate cancer incidence rate in the state is in

West Baton Rouge Parish, with 187.8 cases per 100,000.

"This study is the largest interventional NCI clinical trial for men who present with Stage 4 prostate cancer in the past 25 years," adds Dr. Delacroix. "It has the potential to impact the treatment for men with Stage 4 prostate cancer in multiple ways including not only answering the question of improving survival, but also potentially finding distinct groups of patients with prostate cancers that behave and respond differently to therapies. The National Cancer Institute, Southwest Oncology Group and the national principal investigator Dr. Brian Chapin from the University of Texas MD Anderson Cancer Center should be congratulated for making this trial available to all men with newly diagnosed Stage 4 [prostate cancer](#)."

Provided by Louisiana State University

Citation: Prostate cancer clinical trial seeking Rx approach answers for survival and quality of life (2018, September 25) retrieved 9 April 2024 from

<https://medicalxpress.com/news/2018-09-prostate-cancer-clinical-trial-rx.html>

<p>This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.</p>
--