

Clinical insight improves treatment with new lung cancer drug

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Men experience a marked drop in their testosterone levels when taking a targeted therapy to control a specific type of lung cancer. That's according to a University of Colorado Cancer Center study published in the April issue of *Cancer*, the official journal of the American Cancer Society.

Investigators at CU Cancer Center looked at the [hormone levels](#) in men with anaplastic lymphoma kinase (ALK) positive advanced non-small cell lung cancer (NSCLC) taking crizotinib, after a 35-year-old man on the drug reported symptoms that are often attributed to [low testosterone levels](#): fatigue and sexual disinterest.

Crizotinib tablets were licensed by the [Food and Drug Administration](#) in August 2011, because of its dramatic and long-lasting suppression of ALK positive lung cancer. ALK positive lung cancer was only recently described so very few cancer centers have a lot of experience identifying and treating this subtype of the disease. CU Cancer Center was involved in the initial development of the drug and has treated one of the largest groups of ALK positive patients in the world.

The [testosterone](#) study included 19 men with lung cancer taking crizotinib and 19 men with lung cancer receiving other kinds of therapy. Andrew Weickhardt, MD, senior clinical fellow at the CU Cancer Center, and one of the study's co-authors said listening to the specific issues of that one young man, and a growing awareness of the incidence of low testosterone in [cancer patients](#), made investigators look more closely at their patient population.

"While testosterone was low in only about thirty percent of men on other therapies, it was low in one hundred percent of the men who were on crizotinib. And when we started to track it over time, we could clearly see testosterone levels dropping within days of starting on the drug," said

Weickhardt.

As men may stay on crizotinib for months, or even years, the effects of low testosterone could be profound.

"Low testosterone can reduce [bone density](#) and [muscle strength](#) as well decrease sex drive and increase fatigue and depression. There are many factors associated with a cancer diagnosis that can lower testosterone, but the levels in crizotinib-treated patients were so uniformly low and their direct relationship with starting the therapy meant there was no doubt the drug was contributing to it," said endocrinologist Micol Rothman, MD, co-author of the study. "Fortunately, we can easily test for and treat this condition."

Matt Ellefson, a lung cancer patient from South Dakota who sought out a second opinion from the University of Colorado program, recalls although his cancer was responding to the crizotinib his energy levels seemed very low. Ellefson's physicians quickly confirmed his testosterone was low and prescribed a testosterone replacement gel.

"The testosterone made an incredible difference in my fatigue and endurance. I could actually feel the difference within 48 hours. Within a week, I had more energy throughout the work day, my running times and workouts improved to the point that I have now entered to run a half-marathon later this year," said Ellefson.

"Testing hormone levels and providing testosterone supplements is a simple way to improve the way these men feel," said Weickhardt. "It's not just about sex drive, it's about overall quality of life."

In recent weeks, several studies from the CU Cancer Center have advanced understanding about ALK positive lung cancer. One study published in *Clinical Cancer Research*, a journal of the American Association for Cancer Research

(AACR), reveals that when ALK positive lung cancer eventually mutates to become resistant to crizotinib it does so in different ways. Either the cancer changes the ALK protein so that the crizotinib is ineffective against it or it develops another type of cancer molecule that makes the cancer less dependent on ALK. If the ALK protein changes, it may be vulnerable to a stronger ALK inhibitor. If it combines with another type of cancer molecule, a combination of drugs may be required.

Provided by University of Colorado Denver

Another study published in *Cancer*, shows different these molecular subtypes of non-small cell lung cancer show distinct patterns of spread in the body.

"Every time we make a discovery, whether it's about the biology or the treatment of ALK or any of the many other emerging subtypes of lung cancer, we are a step closer to making lung cancer less of a headline in people's lives," said Cancer Center investigator D. Ross Camidge, MD, PhD, director of the thoracic oncology clinical program at University of Colorado Hospital (UCH). "With the testosterone story, we can see that knowing your patients as people allows a good doctor to spot patterns and make breakthroughs that can really improve how someone with lung cancer feels on a daily basis."

The CU Cancer Center's Thoracic Oncology Program is world renowned for its pioneering treatment of lung cancer. The program includes a multidisciplinary team of specialists and subspecialists working together to establish the best treatment plan for each patient. Advanced molecular profiling of a patient's tumor, combined with an extensive array of standard and experimental treatments available through clinical trials has led to major advances in patient outcomes in the last few years. The program's one-year survival rates for advanced lung cancer consistently run twice as high as the national average. The survival rates at five years run four times higher than the national average.

CU Cancer Center is the lead site for the national Lung Cancer Mutation Consortium, the collaboration of 14 of the nation's elite lung cancer programs. The consortium is profiling ten different molecular abnormalities in [lung cancer](#) and pairing them with specific experimental treatments over the

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