

New clinical trial framework tests 'natural' cures for cancer

May 16 2017

A University of Colorado Cancer Center clinical trial is now recruiting prostate cancer patients who would otherwise be on a watch-and-wait protocol to test the ability of grape seed extract to slow the rise of prostate-specific antigen (PSA), a common marker of prostate cancer progression. The trial is the result of a series of CU Cancer Center studies demonstrating the promise of grape seed extract in preclinical models of prostate cancer, in collaboration with doctors at University of Colorado Hospital who treat the condition. In addition to testing grape seed extract, the trial provides the framework to test other promising compounds in this setting, potentially including additional compounds derived from natural sources.

"In this window, we would only be watching these patients - our trial is an alternative to observation, not an alternative to treatment - and we've shown that grape [seed](#) extract is unlikely to cause side effects. So why not take this opportunity to test some of these promising compounds, starting with grape seed extract?" says Paul Maroni, MD, investigator at the CU Cancer Center and associate professor of Surgery at the CU School of Medicine.

The trial will enroll 40 men with asymptomatic, non-metastatic [prostate cancer](#) with rising PSA, who will take 150 mg of grape seed extract by mouth twice daily. These men will then be evaluated every 6 weeks for a year to measure the progress of their [cancer](#).

"Our hope is that the PSA will not rise as quickly as it has in the past for

this patient," says Maroni. "If we would expect it to go from 1 to 2 in next six months, but it only goes up to 1.5 in the grape seed extract group, that would be a significant improvement. This might help them avoid needing other treatments with side effects."

Because prostate cancer tends to be an especially slow-growing form of the disease, it may only take slowing the disease's acceleration by a small amount to push back the date at which the cancer would be expected to become problematic far past a patient's predicted lifespan.

"For many prostate cancer patients, the goal is to die with the disease rather than from it. We see the potential for grape seed extract to help us reach this goal," Maroni says.

His optimism is built largely on the laboratory work of CU Cancer Center investigator Rajesh Agarwal, PhD, professor in the CU Skaggs School of Pharmacy and Pharmaceutical Sciences. Agarwal's lab has primarily focused on using the tools of molecular medicine to evaluate compounds derived from natural products in the same ways that researchers would evaluate any promising anti-cancer agent.

For example, Agarwal's 2012 paper in the journal *Carcinogenesis* shows that grape seed extract creates oxidative stress that damages cancer cell DNA and also interrupts the pathways that would repair this damage (as seen by decreased levels of the DNA repair molecules Brca1 and Rad51 and DNA repair foci). A 2015 paper in the journal *Molecular Carcinogenesis* looks even closer at this mechanism to show how grape seed extract initiates this oxidative stress, namely by targeting the energy-producing mitochondria in cancer cells. Another 2015 paper, in *Current Cancer Drug Targets*, shows that grape seed extract targets prostate cancer progenitor cells by slowing their ability to grow new blood vessels needed to supply the cancer with nutrients.

"I think the whole point is that cancer cells have a lot of defective pathways and they are very vulnerable if you target those pathways. The same is not true of healthy cells," Agarwal says.

The Agarwal lab has followed this line of reasoning to show that grape seed extract does indeed use these mechanisms to slow the growth of cancers in mouse models, setting the stage for the current clinical trial which will test, for the first time, the effect of grape seed extract in human cancer patients.

In fact, ongoing work at the Agarwal lab is unpacking mechanics of a few other compounds derived from natural sources including milk thistle extract and bitter melon.

"Ultimately, if grape seed doesn't change how we approach these patients, then we've built a program to examine other complimentary or low-side-effect medicines. If [grape seed extract](#) doesn't work, we can take this protocol, put in a new background - bitter melon, milk thistle, etc. - and examine that," Maroni says.

Many drugs currently used against cancer originated from substances found naturally. Now this approach that uses the tools of Western medicine to evaluate what some would consider Eastern ideas may allow doctors to add to this list of naturally-derived compounds that aid our fight against cancer.

Provided by CU Anschutz Medical Campus

Citation: New clinical trial framework tests 'natural' cures for cancer (2017, May 16) retrieved 10 April 2024 from

<https://medicalxpress.com/news/2017-05-clinical-trial-framework-natural-cancer.html>

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