

Drug trio shows major promise against myeloma

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(HealthDay)—Adding a newer drug to a standard treatment for advanced

cases of multiple myeloma may significantly boost patients' chances of a response and even recovery, a new clinical trial finds.

Of patients given the drug, called daratumumab, 43 percent had a complete response—meaning there were no signs of the cancer left. That compared with 19 percent of patients who received a standard drug duo alone.

And over 13.5 months, the daratumumab combination cut patients' risk of dying or seeing their cancer progress by 63 percent, the study found.

Researchers called the results "unprecedented" for patients like these. All had relapsed or refractory myeloma—which means the cancer had either come back or failed to respond to the previous treatment.

"It is very likely that (this regimen) will be rapidly adopted by practicing physicians," said lead researcher Dr. Meletios Dimopoulos, a professor at the National and Kapodistrian University of Athens, in Greece.

Dr. Vincent Rajkumar, a cancer specialist at the Mayo Clinic in Rochester, Minn., said he is one of them.

The three-drug combo will be his "first choice" for myeloma patients who suffer a first-time relapse, Rajkumar said.

He wrote an editorial published with the findings in the Oct. 6 issue of the *New England Journal of Medicine*.

Multiple myeloma is a cancer that begins in certain white blood cells. In the United States, it accounts for less than 2 percent of cancers. But, for those who do develop it, it's often deadly: Only about 48 percent of Americans with the disease are still alive five years after diagnosis, according to the U.S. National Cancer Institute.

Even when myeloma patients initially respond to treatment, the cancer usually comes back.

So it's important to have a range of treatment options when that happens, Rajkumar explained. "We need new drug classes that work differently from one another," he said.

Fortunately, a number of new drugs have come onto the market in just the past few years, Dimopoulos said.

Daratumumab, sold as Darzalex, is one of them. It was approved in the United States last year, after trials showed that the drug, given alone, can shrink tumors in patients with relapsed or refractory myeloma.

The new trial tested the effects of adding daratumumab to two standard drugs: lenalidomide (Revlimid) and dexamethasone.

The researchers recruited 569 myeloma patients and randomly assigned them to receive either lenalidomide and dexamethasone alone, or the three-drug regimen.

Over almost 14 months, 41 percent of the patients in the standard-treatment group either died or saw their cancer progress. That compared with only 18.5 percent of patients given all three drugs.

Daratumumab also more than doubled the rate of complete response: 43 percent, versus 19 percent.

The drug, which is given by infusion, latches onto a specific protein on myeloma cells called CD38. It's thought to work by both killing the [cancer](#) cells directly and helping the immune system attack them.

But there are side effects, too. According to the U.S. Food and Drug

Administration, the most common ones include infusion-related reactions, fatigue, nausea, back pain and fever.

The drug can also lower patients' blood cell counts—which may leave them vulnerable to infections, anemia or excessive bleeding and bruising.

Then there are the rigors, and cost, of treatment. Daratumumab requires weekly infusions to start, then tapers off to a monthly one. In this study, as in other myeloma studies, the whole regimen was continued indefinitely, until patients progressed or quit because of side effects.

As for the price, Darzalex alone reportedly costs close to \$5,900 per dose.

From a "quality-of-life and economic standpoint," Rajkumar said, that is not ideal.

"We really need trials that ask, can we treat patients for one year, then stop for a time?" he said.

Another question, according to Rajkumar, is how well the current findings will translate to U.S. patients: The trial enrolled patients from 18 countries, most of whom had never receive lenalidomide before.

In the United States, Rajkumar said, most patients with relapsed myeloma would have already received lenalidomide. He added, though, that those relapsed patients would not necessarily be resistant to a treatment containing lenalidomide.

Despite the questions, Rajkumar called the trial findings the "most promising" in years.

"I have no doubt this (regimen) will significantly extend progression-free survival for myeloma [patients](#)," he said.

Janssen Biotech, which markets Darzalex, funded the study. Dimopoulos and some of the co-researchers have served on the company's advisory board.

More information: The American Cancer Society has more on [multiple myeloma](#).

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