

'Red yeast rice' statin alternative not harmless either, study says

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(HealthDay)—A natural cholesterol-lowering supplement called red

yeast rice could pose the same health risks to users as statin drugs, a new study contends.

Red yeast rice could increase risk of muscle injury or liver damage, Italian researchers reported after reviewing 13 years of patient data.

"These findings raise the hypothesis that the safety profile of red yeast rice is highly similar to that of synthetic [statins](#) and warrants further investigations to finally characterize the safety profile of red yeast rice," the researchers concluded.

American heart experts said it's not surprising that the researchers discovered [adverse reactions](#) to red yeast rice that are similar to those produced by statins.

That's because one of the compounds in red yeast rice—monacolin K—has the same chemical structure as the statin drug lovastatin, said Dr. Paul Thompson.

"Statins actually exist in nature, in fungi and molds and stuff like that," said Thompson, an American College of Cardiology fellow. "Patients need to know there is lovastatin in this product." (Brand names for lovastatin are Mevacor and Altoprev.)

However, the new report only details 55 reports of adverse reactions during the entire study period. To Thompson, this indicates they are "a very rare problem."

"It's a tempest in a teapot," Thompson said of the new study.

Red yeast rice is concocted from yeast grown on rice. U.S. sales of red yeast rice dietary supplements totaled about \$20 million a year in both 2008 and 2009, the most recent years for which data are available,

according to the U.S. National Center for Complementary and Integrative Health (NCCIH).

The U.S. Food and Drug Administration views red yeast rice products containing more than trace amounts of monacolin K as unapproved new drugs, since they are chemically identical to lovastatin, and cannot be sold legally as dietary supplements.

But dozens of red yeast rice products remain on the market. And products tested as recently as 2011 have been found to contain monacolin K in substantial amounts, the NCCIH says.

For the new study, the Italian researchers reviewed government data collected on natural health products between April 2002 and September 2015.

Reports of muscle pain came from 19 patients, including some who experienced an increase in levels of creatine phosphokinase, an enzyme released when muscle tissue is damaged, the researchers said.

Thirteen of 14 "serious" cases required hospitalization. Ten patients suffered liver damage, the researchers found.

In addition, 12 patients reported gastrointestinal reactions that included upset stomach, nausea, vomiting and diarrhea.

The researchers noted that muscle pain and [liver damage](#) are common side effects of statins, which countless people take to lower their cholesterol and their risk of heart attack and stroke.

But Thompson said the study doesn't directly tie the red yeast rice to any of these health problems.

"There's no way to be absolutely guaranteed certain that most of these cases were related to the red yeast rice," he said. Thompson is chief of cardiology at Hartford Hospital in Connecticut.

Patients with high cholesterol often buy red yeast rice over the counter when they're concerned about the side effects of prescription statins, said Dr. Robert Eckel, a spokesman for the American Heart Association.

"You have to let them know that, well, you're actually taking a statin," said Eckel, who's also a professor at the University of Colorado School of Medicine.

The Council for Responsible Nutrition, a supplement manufacturer trade group, recommends that people talk with their doctor before taking red yeast rice to lower cholesterol.

"For the small percentage of people who may have an adverse response to red yeast rice, a doctor can help to determine whether it can be tolerated, and if not, to seek other alternatives," said Duffy MacKay. He's the council's senior vice president of scientific and regulatory affairs.

Some clinical trials have shown that people with a history of statin intolerance seem to tolerate red yeast rice, Eckel said.

Thompson said he prescribes a fair amount of red yeast rice in his clinic as a way to ease reluctant patients into statin treatment.

But because it's a supplement, the amount of active ingredient in [red yeast rice](#) can vary widely from brand to brand and even batch to batch, Thompson and Eckel said.

"The products are not as well-controlled and the dosages are variable,"

Eckel said.

Red yeast rice also can prove expensive if taken regularly, because it isn't covered by insurance, Thompson said.

"My advice is people should take regular statins, even if they have to take it at very low doses," Thompson said.

The new study appears in the *British Journal of Clinical Pharmacology*.

More information: G. Mazzanti et al. Adverse reactions to dietary supplements containing red yeast rice: assessment of cases from the Italian surveillance system, *British Journal of Clinical Pharmacology* (2016). [DOI: 10.1111/bcp.13171](https://doi.org/10.1111/bcp.13171)

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