Milk Thistle Shows No Benefit in Hep C Treatment Trial

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Milk thistle (Silybum marianum), a popular herbal dietary supplement used by many people with liver disease, works no better than placebo in patients with chronic hepatitis C, according to clinical trial results published in the July 18 issue of The Journal of the American Medical Association (JAMA).

Silymarin (a flavonoid) is the active ingredient in milk thistle, a plant native to the Mediterranean region. Laboratory studies have shown that it has antioxidant and anti-inflammatory properties, potentially explaining its popularity as a complementary therapy for liver, kidney and other problems.

Milk thistle's documented effectiveness is checkered, however. Results from clinical trials, particularly involving people living with chronic hep C, have been mixed.To explore milk thistle's potential, Michael Fried, MD, of the University of North Carolina School of Medicine and his colleagues conducted a clinical trial involving 154 people living with hepatitis C who were unable to clear the virus after receiving therapy with a pegylated interferon-based regimen.

Study volunteers were randomized to receive one of two doses of silymarin—either 420 or 720 milligrams (mg)—or matching placebo, three times a day for 24 weeks.

At the end of the six-month study, only two patients in each of the three treatment groups met the main outcome measure of the study, which was normalization or a 50 percent or greater decline in alanine aminotransferase (ALT) levels, compared with those seen at the start of the study.

Though average ALT levels tended to drop more in the silymarin group, compared with the placebo group, the differences were not statistically significant, meaning they could have been due to chance.

Liver biopsies were not conducted as part of the study, thus the researchers were unable to determine if silymarin had any effect on fibrosis progression.

When looking at average hepatitis viral loads and quality-of-life measurements, all three groups were comparable—silymarin didn't significantly affect these variables.

"This was the strongest, most methodologically sound clinical trial to date of silymarin as a

treatment for chronic hepatitis C infection, and we found that it had absolutely no effect on serum ALT or levels of the hepatitis C virus," Fried said in an accompanying news release. "That was a surprise to us. We expected it to show at least some effect."

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