

New drug for common liver disease improves liver health

November 6 2014

An experimental drug aimed at treating a common liver disease showed promising results and potential problems in a multicenter clinical trial funded by the National Institutes of Health. The FLINT study found that people with [nonalcoholic steatohepatitis \(NASH\)](#) who took obeticholic acid (OCA) had improved liver health during that period, including decreased inflammation and fat in the liver and decreased body weight versus people receiving a placebo. OCA was also associated with increases in itching and total cholesterol.

The findings of FLINT, or the Farnesoid X Receptor Ligand Obeticholic Acid in NASH Treatment Trial, were published online Nov. 6 in *The Lancet*. FLINT was sponsored by the NIH's National Institute of Diabetes and Digestive and Kidney Diseases.

"NASH is a common and potentially serious disease that currently has no approved treatment. Management typically includes weight loss through diet and exercise," said Averell Sherker, M.D., NIDDK program official for the NASH Clinical Research Network (NASH CRN), which performed the FLINT study.

Liver health improved in 45 percent of people on OCA versus 21 percent of the placebo group. "Although obeticholic acid did not eliminate [liver disease](#) in FLINT participants, it demonstrated a promising effect. Larger studies will be required to determine the drug's safety and efficacy," Sherker said.

FLINT enrolled 283 people at eight centers across the country. At the study's start, participants were 18 and older and had been diagnosed with definite or borderline NASH. They were randomly assigned to one of two groups: one took 25 milligrams of OCA daily and one received a placebo that resembled the OCA pill. The study was double-blinded, so neither participants nor investigators knew which person was in which group.

Trial investigators intended for the groups to receive the drug or placebo for 72 weeks, with an additional 24 weeks of follow-up off treatment. However, planned interim analysis for safety and efficacy showed that OCA had significant beneficial effects on NASH-related liver health.

The analysis also found unanticipated increases in total [cholesterol](#) in the OCA group. They had increased LDL cholesterol ("bad" cholesterol) and decreased HDL cholesterol ("good" cholesterol) - notable because NASH patients are already at higher risk for cardiovascular diseases. As cholesterol treatment was not standardized as part of the study, further research is needed to fully understand the potential effect of OCA on cholesterol.

Because of both factors, and with the concurrence of the Data Safety and Monitoring Board, NIDDK decided to stop treatment but continue the study, move all patients into the follow-up phase, and perform no additional liver biopsies - which carry their own risks. Adverse cholesterol increases were not sustained after stopping OCA.

"The FLINT trial represents an important advance in the search for treatments of NASH. The causes of NASH are not fully understood, and causes and treatments may be different among patients," said the study's lead author, Brent Neuschwander-Tetri, M.D., a professor at St. Louis University. "We need to study the changes in cholesterol levels more to know if the increases caused by obeticholic acid increase the risk of

hardening of the arteries. We found that the improvement in liver enzymes with obeticholic acid were not sustained after treatment was stopped, so we would expect that treatment would need to be indefinite, much like the medications for diabetes and hypertension."

The major feature of NASH is fat in the liver, along with inflammation and damage. Over time, these may lead to loss of liver function, the need for liver transplantation and death. NASH may have no symptoms and can only be diagnosed with a liver biopsy. Beyond maintaining a healthy weight, people with NASH are advised to avoid alcohol and unnecessary medications. New cases of NASH have grown alongside the obesity epidemic. NASH is the third leading diagnosis requiring U.S. [liver](#) transplantation.

Provided by National Institute of Diabetes and Digestive and Kidney Diseases

Citation: New drug for common liver disease improves liver health (2014, November 6) retrieved 27 April 2024 from

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