Will NASH Treatments Succeed?

A number of treatments for non-alcoholic steatohepatitis (NASH) have shown promise in recent mid-stage trials.

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Currently, there are no approved medications for advanced fatty liver disease. But a number of treatments for non-alcoholic steatohepatitis (NASH) have shown promise in recent mid-stage trials.

A Phase IIb trial randomly assigned nearly 400 people with NASH and liver fibrosis to receive a placebo or one of three oral doses of Cirius Therapeutics' insulin-sensitizing drug MSDC-0602K. After 12 weeks, those who received the two higher doses saw improved glucose metabolism and insulin resistance as well as lower ALT, AST and GGT liver enzyme and alkaline phosphatase levels, which are tied to liver damage and inflammation. However, MSDC-0602K did not improve liver health according to biopsies.

Two different doses of Novartis's FXR agonist tropifexor are under investigation in an ongoing Phase II trial of 48 weeks of treatment in 152 people with NASH and moderate to severe fibrosis. Results at the 12-week mark showed that the highest dose was associated with a rapid decline in participants' ALT and GGT levels and a reduction in liver fat content. Both tropifexor doses were associated with weight loss, lower LDL (bad) cholesterol and higher HDL (good) cholesterol.

Another Novartis drug, licogliflozin, was studied at two doses in a Phase IIa trial among 77 people who either had NASH and fibrosis or were overweight, had type 2 diabetes and a high ALT level. After 12 weeks, the higher dose led to a decline in ALT, while AST, GGT and HbA1c blood glucose levels and liver fat content declined in both dose groups.

Lastly, a Phase II trial of three doses of Zydus's saroglitazar included 106 people with different stages of fatty liver disease. After 16 weeks, all doses led to a decline in ALT and liver fat content, while insulin resistance and fasting insulin decreased only in the highest-dose group.

Further research in larger trials will help determine whether these drugs offer long-term clinical benefits rather than just biomarker improvements as well as whether they may be useful as part of combination treatment with other medications.

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