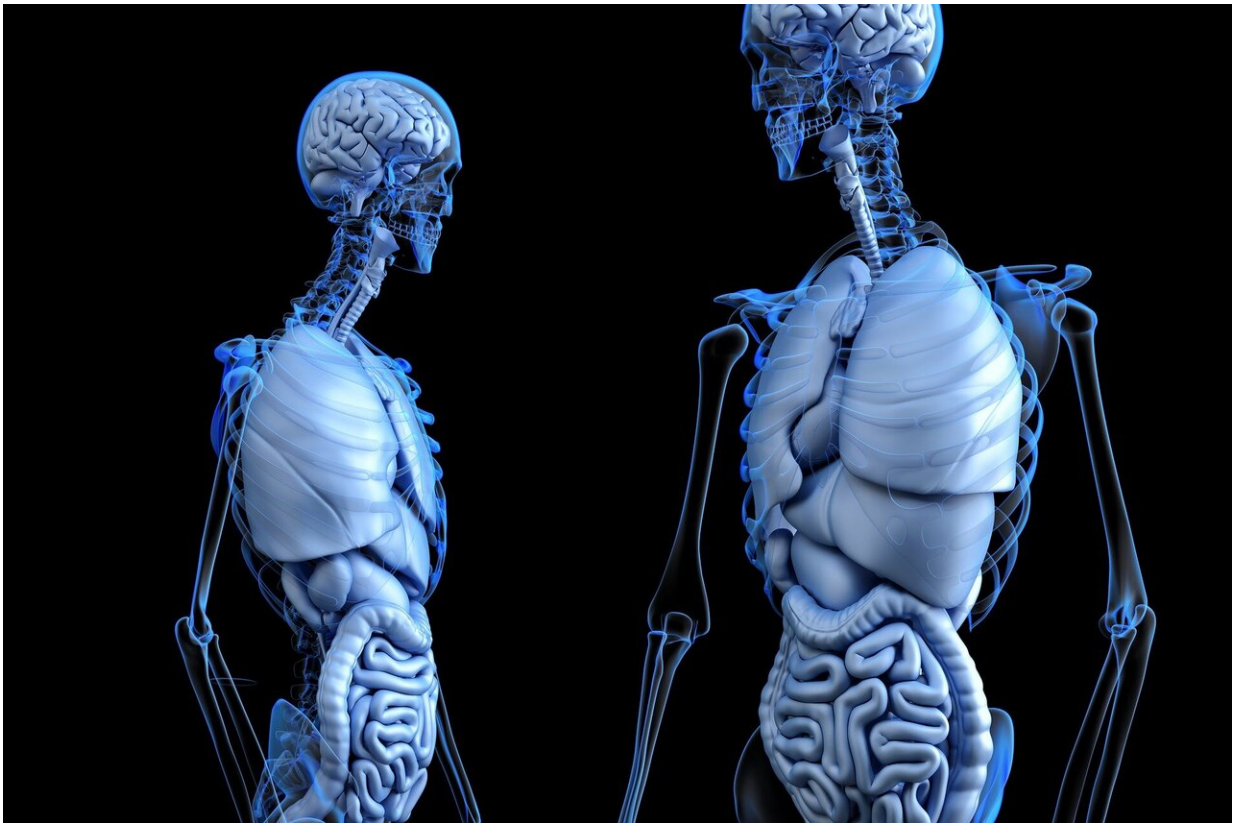


# New treatment option for nonalcoholic fatty liver disease

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A team led by Michael Trauner at MedUni Vienna's Division of Gastroenterology and Hepatology demonstrated the beneficial effect of synthetically produced bile acid with the active agent nor-

ursodeoxycholic acid (nor-urso) in the hitherto incurable liver disease primary sclerosing cholangitis (PSC) around two years ago. A recent trial has now shown that nor-urso is also an effective treatment option for nonalcoholic fatty liver disease. The results were recently published in leading journal *The Lancet Gastroenterology & Hepatology*.

More than a quarter of the Austrian population suffers from a form of [nonalcoholic fatty liver disease](#), usually caused by a poor lifestyle with too much fatty and sugary food and too little exercise, which goes hand-in-hand with obesity. Between 35 percent and 50 percent of people in the 50 to 60 age group already have a fatty [liver](#). Fatty liver disease is a so-called silent condition that is usually only discovered by accident. However, the long-term consequences can be serious and can lead to cirrhosis and cancer of the liver. Around 10 to 30 percent of all fatty liver diseases are classified as the most dangerous form of fatty liver steatohepatitis/NASH, which in turn develops into cirrhosis of the liver in 15 to 25 percent of cases.

"The Phase IIa trial of nor-urso that we have recently completed with help from numerous Austrian and German centres shows positive results when used in nonalcoholic [fatty liver disease](#)," says lead author of the study Stefan Traussnigg from MedUni Vienna's Department of Medicine III. Synthetically produced bile acid protects the liver from inflammation, which could then culminate in fibrosis. The researchers use the hormone effect of the bile acid as a target.

Trauner says, "The bile acid circulates through the body like a steroid hormone and regulates many metabolic processes. In fatty liver disease, it is as if a bile-acid-signal resistance develops, so that these processes no longer function properly. Nor-urso re-intensifies the hormone effect of the bile acid." This gives patients a much better prognosis for the further course of the disease.

The MedUni Vienna researchers now want to conduct further studies to test whether nor-urso also helps to inhibit the commonest causes of death in fatty liver [disease](#), namely cardiovascular diseases such as heart attacks or strokes, thereby improving life expectancy in general. "It would be logical to expect that—and we are optimistic. But we have not yet verified it," says Trauner.

## Personalised medicine in hepatology

At the same time, the hepatologists at MedUni Vienna have developed two further therapy options using bile acid, which have already been prominently publicised. A further approach targets the activation of the bile acid receptor FXR (a sensor for bile acid). This receptor is involved in important processes such as regulation of lipid and glucose metabolism and the synthesis and circulation of bile acid. Thus, the long-term data from a Phase III trial on the use of obeticholic acid in primary biliary cholangitis (PBC), as the first clinically available FXR ligand, were published this year. Says Trauner, "This was recently approved as a second-line treatment for PBC and has also shown beneficial effects in [fatty liver](#)/NASH."

In addition to obeticholic [acid](#), there are already other new FXR activators or ligands available, which do not have a [bile acid](#) structure (so-called non-steroidal FXR ligands) and which are therefore better tolerated. These could likewise produce the first positive results in primary biliary cholangitis. "These promising options now give us three further possibilities for individual treatment, in the spirit of personalised medicine, utilising the signal properties and hormone effects of bile acids. In future, we will be able to use these in combination to help patients," underscores Trauner.

**More information:** Stefan Traussnigg et al. Norursodeoxycholic acid versus placebo in the treatment of non-alcoholic fatty liver disease: a

double-blind, randomised, placebo-controlled, phase 2 dose-finding trial, *The Lancet Gastroenterology & Hepatology* (2019). DOI: [10.1016/S2468-1253\(19\)30184-0](https://doi.org/10.1016/S2468-1253(19)30184-0)

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