

Diabetes drug shows promise in the treatment of non-alcoholic steatohepatitis

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A drug approved to treat type 2 diabetes could prove to be a powerful new treatment option for non-alcoholic steatohepatitis (NASH), according to research presented today at The International Liver Congress 2015. Results from a randomised controlled trial showed liraglutide met the primary endpoint of histological clearance of NASH, and a reduction in the progression of fibrosis. The research was supported by the Wellcome Trust and the NIHR.

In the Liraglutide Efficacy and Action in NASH (LEAN) trial, [overweight patients](#) with biopsy-confirmed NASH were randomised (1:1) to receive a 48-week treatment with once-daily, subcutaneous injections of either 1.8 mg liraglutide or liraglutide-placebo (control). The primary outcome was improvement in [liver](#) histology, defined as 'resolution of definite NASH' and no worsening in fibrosis from baseline to end-of-treatment.

Of the 52 randomised patients, 45 underwent end-of-treatment liver biopsies. The primary endpoint was met, and 9 (39%) of 23 patients on liraglutide had resolution of definite NASH with no worsening of fibrosis compared to 2 (9%) of the 22 patients on placebo. Only 2 (9%) patients on liraglutide had worsening of fibrosis compared to 8 (36%) on placebo. Moreover, liraglutide was shown to reduce weight, BMI and fasting glucose compared to placebo. There were no drug-related serious adverse events in patients on liraglutide.

Dr Matthew Armstrong, LEAN co-investigator, NIHR Birmingham Liver Biomedical Research Unit, University of Birmingham, commented: "Although NASH is the most common cause of chronic liver disease, there are still no licensed drugs to treat it. Results from the LEAN trial are a major breakthrough and point towards a potential treatment option for this disease. A Phase 3 trial is now needed to confirm the potential of this class of medication, known as human glucagon-like

peptide-1 analogues, as a valid therapeutic option for patients with NASH."

Professor Philip Newsome, LEAN Chief Investigator, NIHR Birmingham Liver Biomedical Research Unit, University of Birmingham, added: "Clearance of NASH in this study was very encouraging and means we are a step closer to new treatments for [patients](#) suffering with non-alcoholic fatty liver disease."

"NASH occurs when the liver becomes inflamed due to the accumulation of fat. Over time, persistent inflammation can lead to the formation of fibrous scar tissue in the liver and around its blood vessels, which can eventually cause cirrhosis. In Europe, the prevalence of NASH is approximately 5% so we welcome the ongoing research and development in this area to help the millions of people affected by this disease," said Professor Markus Peck, Secretary General, European Association for the Study of the Liver.

Provided by European Association for the Study of the Liver

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