



A randomized controlled trial of high-dose ursodesoxycholic acid for nonalcoholic steatohepatitis

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Résumé en anglais

Background & Aims Nonalcoholic steatohepatitis (NASH) is a prevalent liver disease associated with increased morbidity and mortality. Ursodeoxycholic acid (UDCA) may have antioxidant, anti-inflammatory, and antifibrotic properties and may reduce liver injury in NASH. To date, no studies have assessed the efficacy and safety of high-dose UDCA (HD-UDCA) in patients with NASH. **Methods** We conducted a 12-month, randomized, double-blind, placebo-controlled multicenter trial to evaluate the efficacy and safety of HD-UDCA (28–35 mg/kg per day) in 126 patients with biopsy-proven NASH and elevated alanine aminotransferase (ALT) levels. The primary study end point was reduction in ALT levels from baseline in patients treated with HD-UDCA compared with placebo. Secondary study end points were the proportion of patients with ALT normalization, relative reduction in the scores of serum markers of fibrosis and hepatic inflammation, and safety and tolerability. **Results** HD-UDCA significantly reduced mean ALT levels –28.3% from baseline after 12 months compared with –1.6% with placebo ($p < 0.001$). At the end of the trial, ALT levels normalized (≤ 35 IU/L) in 24.5% of patients treated with HD-UDCA and in 4.8% of patients who received placebo ($p = 0.003$). Both results were not accounted for by changes in weight during the trial. HD-UDCA significantly reduced the FibroTest® serum fibrosis marker ($p < 0.001$) compared with placebo. HD-UDCA also significantly improved markers of glycemic control and insulin resistance. There were no safety issues in this population. **Conclusions** Treatment with HD-UDCA was safe, improved aminotransferase levels, serum fibrosis markers, and selected metabolic parameters. Studies with histologic end points are warranted.

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