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A large-scale, multicentre, double-blind trial of ursodeoxycholic acid in patients with chronic hepatitis C.

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Abstract

BACKGROUND: Combined pegylated interferon and ribavirin has improved chronic hepatitis C (CH-C) therapy; however, sustained virological response is achieved in only about half of the patients with a 1b genotype infection. We assessed oral ursodeoxycholic acid (UDCA) on serum biomarkers as a possible treatment for interferon non-responders.

METHODS: CH-C patients with elevated alanine aminotransferase (ALT) were assigned randomly to 150 (n = 199), 600 (n = 200) or 900 mg/day (n = 197) UDCA intake for 24 weeks. Changes in ALT, aspartate aminotransferase (AST) and gamma-glutamyl transpeptidase (GGT) were assessed. This study is registered at ClinicalTrial.gov, identifier [NCT00200343](https://clinicaltrials.gov/ct2/show/study?term=NCT00200343).

RESULTS: ALT, AST and GGT decreased at week 4 and then remained constant during drug administration. The median changes (150, 600 and 900 mg/day, respectively) were: ALT, -15.3, -29.2 and -36.2%; AST, -13.6, -25.0 and -29.8%; GGT, -22.4, -41.0 and -50.0%. These biomarkers decreased significantly less in the 150 mg/day than in the other two groups. Although changes in ALT and AST did not differ between the 600 and 900 mg/day groups, GGT was significantly lower in the 900 mg/day group. In subgroup analysis, ALT decreased significantly in the 900 mg/day group when the baseline GGT exceeded 80 IU/l. Serum HCV-RNA did not change in any group. Adverse effects were reported by 19.1% of the patients, with no differences between groups.

CONCLUSIONS: A 600 mg/day UDCA dose was optimal to decrease ALT and AST levels in CH-C patients. The 900 mg/day dose decreased GGT levels further, and may be preferable in patients with prevailing biliary injuries.

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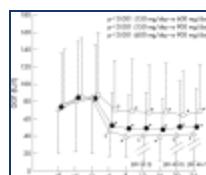
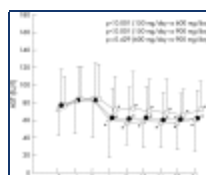
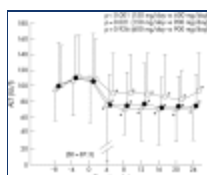
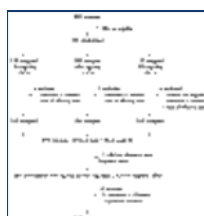
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