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[Aspartate-ornithine granules in the treatment of nonalcoholic steatohepatitis: a multiple-dose parallel controlled clinical trial]

[Article in Chinese]

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Abstract

Objective: To investigate the therapeutic efficacy and safety of aspartate-ornithine granules in patients with nonalcoholic steatohepatitis (NASH).

Methods: Seventy-two patients with NASH were included in this multiple-dose parallel controlled clinical trial and received a 12-week course of aspartate-ornithine granule treatment at either high-dose (6 g bid po; n = 38) or low-dose (3 g bid po; n = 34). Clinical efficacy was assessed by monitoring data from urinalysis, serologic tests (alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma-glutamyl transferase (GGT), and triglyceride (TG)), and abdominal computed tomography (CT) scan. Safety was assessed by occurrence of adverse events (fatigue, anorexia, abdominal distension, nausea, and vomiting). Statistical analyses were conducted to determine the significance of differences between parameters before (baseline) and after treatment.

Results: After 12 weeks of treatment, the liver and spleen CT ratios in both the high-dose group (0.89 +/- 0.19) and the low-dose group (0.80 +/- 0.15) were significantly

higher than at baseline ($S = 329$, P less than 0.0001 and $S = 246$, P less than 0.0001); the overall improvement was more robust in the high-dose group (52.63%) than in the low-dose group (38.23%) ($Z = -2.1042$, P less than 0.05). After 6 and 12 weeks of treatment, the serum ALT levels in both the high-dose group and the low-dose group were significantly lower than at baseline (6 weeks: $S = 324.5$, P less than 0.0001 and $S = 223$, P less than 0.0001; 12 weeks: $S = 370.5$, P less than 0.0001 and $S = 297.5$, P less than 0.0001); the overall improvement was more robust in the high-dose group (79.0%) than in the low-dose group (53.0%) ($Z = -2.0533$, P less than 0.05). Similar trends were seen for the serum levels of AST and GGT after 6 and 12 weeks of treatment (all P less than 0.01) and serum levels of TG after 12 weeks of treatment. The rate of adverse reactions was low and similar between the two groups (high-dose: 4.8% and low-dose: 4.4%; all gastrointestinal).

Conclusion: Aspartate-ornithine granule therapy was an effective and safe treatment of nonalcoholic steatohepatitis, with the higher dose of 6 g bid po providing more robust clinical benefit without affecting the safety profile.