A Placebo-Controlled Trial of Bezafibrate in Primary Biliary Cholangitis

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Résumé en anglais	BACKGROUND: Patients with primary biliary cholangitis who have an inadequate response to therapy with ursodeoxycholic acid are at high risk for disease progression. Fibrates, which are agonists of peroxisome proliferator-activated receptors, in combination with ursodeoxycholic acid, have shown potential benefit in patients with this condition. METHODS: In this 24-month, double-blind, placebo-controlled, phase 3 trial, we randomly assigned 100 patients who had had an inadequate response to ursodeoxycholic acid according to the Paris 2 criteria to receive bezafibrate at a daily dose of 400 mg (50 patients), or placebo (50 patients), in addition to continued treatment with ursodeoxycholic acid. The primary outcome was a complete biochemical response, which was defined as normal levels of total bilirubin, alkaline phosphatase, aminotransferases, and albumin, as well as a normal prothrombin index (a derived measure of prothrombin time), at 24 months. RESULTS: The primary outcome occurred in 31% of the patients assigned to bezafibrate and in 0% assigned to placebo (difference, 31 percentage points; 95% confidence interval, 10 to 50; P<0.001). Normal levels of alkaline phosphatase were observed in 67% of the patients in the bezafibrate group and in 2% in the placebo group. Results regarding changes in pruritus, fatigue, and noninvasive measures of liver fibrosis, including liver stiffness and Enhanced Liver Fibrosis score, were consistent with the results of the primary outcome. Two patients in each group had complications from end-stage liver disease. The creatinine level increased 5% from baseline in the bezafibrate group and decreased 3% in the placebo group. Myalgia occurred in 20% of the patients in the bezafibrate group and in 10% in the placebo group. CONCLUSIONS: Among patients with primary biliary cholangitis who had had an inadequate response to ursodeoxycholic acid alone, treatment with bezafibrate in addition to ursodeoxycholic acid resulted in a rate of complete biochemical response that was significantly higher than the rate with placebo and ursodeoxycholic acid therapy. (Funded by Programme Hospitalier de Recherche Clinique and Arrow Génériques; BEZURSO ClinicalTrials.gov number, NCT01654731 .).
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