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Randomised, placebo-controlled, double-blind clinical trial of beta-sitosterol in patients with benign prostatic hyperplasia. Beta-sitosterol Study Group.

Berges RR[1], Windeler J, Trampisch HJ, Senge T.

Author information : Department of Urology, Ruhr-University, Bochum, Germany.

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Abstract

Medical treatments have become available for benign hypertrophy of the prostate, including alpha-receptor blocking agents and 5-alpha-reductase inhibitors. Drugs derived from plants, for which no precise mechanism of action has been described, are widely used for this purpose in Europe. In a randomised, double-blind, placebo-controlled multicentre study, 200 patients (recruited between April and October 1993) with symptomatic benign prostatic hyperplasia were treated with either 20 mg beta-sitosterol (which contains a mixture of phytosterols) three times per day or placebo. Primary end-point was a difference of modified Boyarsky score between treatment groups after 6 months; secondary end-points were changes in International Prostate Symptom Score (IPSS), urine flow, and prostate volume. Modified Boyarsky score decreased significantly with a mean of -6.7 (SD 4.0) points in the beta-sitosterol-treated group versus -2.1 (3.2) points in the placebo group $p < 0.01$. There was a decrease in IPSS (-7.4 [3.8] points in the beta-sitosterol-treated group vs -2.1 [3.8] points in the placebo group) and changes in urine flow parameters: beta-sitosterol treatment resulted in increasing peak flow (15.2 [5.7] mL/s from 9.9 [2.5] mL/s), and decrease of mean residual urinary volume (30.4 [39.9] mL from 65.8 [20.8] mL). These parameters did not change in the placebo group ($p < 0.01$). No relevant reduction of prostatic volume was observed in either group. Significant improvement in symptoms and urinary flow parameters show the effectiveness of beta-sitosterol in the treatment of benign prostatic hyperplasia.