

A multicentric, placebo-controlled, double-blind clinical trial of beta-sitosterol (phytosterol) for the treatment of benign prostatic hyperplasia. German BPH-Phyto Study group.

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Abstract

OBJECTIVE:

To report the results of a double-blind, placebo-controlled trial to evaluate Azuprostat, a beta-sitosterol, in patients with symptoms of outlet obstruction caused by benign prostatic hyperplasia (BPH).

PATIENTS AND METHODS:

A randomized, double-blind and placebo-controlled clinical trial was conducted to assess the efficacy and safety of 130 mg free beta-sitosterol (phytosterol) daily, using the international prostate symptom score (IPSS) as the primary outcome variable. In total, 177 patients with BPH were recruited for 6 months of treatment in 13 study centres. In addition to the relative difference in the IPSS, changes in quality of life, peak urinary flow rate (Q_{max}) and post-void residual urinary volume (PVR) were recorded. The drug used in the trial consisted of a chemically defined extract of phytosterols, derived for example from species of *Pinus*, *Picea* or *Hypoxis*, with beta-sitosterol as the main component.

RESULTS:

There were significant ($P < 0.01$) improvements over placebo in those treated with beta-sitosterol; the mean difference in the IPSS between placebo and beta-sitosterol, adjusted for the initial values, was 5.4 and in the quality-of-life index was 0.9. There were also significant improvements in the secondary outcome variables, with an increase in Q_{max} (4.5 mL/s) and decrease in PVR (33.5 mL) in favour of beta-sitosterol when adjusted for the changes after placebo.

CONCLUSION:

These results show that beta-sitosterol is an effective option in the treatment of BPH.