Objective: To report the results of a double-blind, placebo-controlled trial to evaluate b-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 b-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 (Qmax) 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 b-sitosterol as the main component.

Results: There were significant (P<0.01) improvements over placebo in those treated with b-sitosterol; the mean difference in the IPSS between placebo and b-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 Qmax (4.5 mL/s) and decrease in PVR (33.5 mL) in favour of b-sitosterol when adjusted for the changes after placebo.

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