

1: Br J Urol. 1997 Sep;80(3):427-32.

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

Klippel KF, Hiltl DM, Schipp B.

Department of Urology, Allgemeines Krankenhaus Celle, Academic Hospital, Germany.

**OBJECTIVE:** To report the results of a double-blind, placebo-controlled trial to evaluate Azuprostal, 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<sub>max</sub>) 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<sub>max</sub> (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.

1: BJU Int. 2000 May;85(7):842-6.

Treatment of symptomatic benign prostatic hyperplasia with beta-sitosterol: an 18-month follow-up.

Berges RR, Kassen A, Senge T.

Department of Urology, Ruhr-University of Bochum, Herne, Germany.

**OBJECTIVES:** To determine the long-term effects of phytotherapy with beta-sitosterol (the trade name for beta-sitosterol used in this study is Harzol(R)) for symptomatic benign prostatic hyperplasia (BPH). **Patient and methods** At 18 months after enrolment in a 6-month multicentre double-blind placebo-controlled clinical trial with beta-sitosterol (reported previously), patients were re-evaluated using the modified Boyarsky score, the International Prostate Symptom Score and quality-of-life index, the maximum urinary flow rate (Q<sub>max</sub>) and postvoid residual urine volume (PVR). In this open extension of the original trial (after 6 months of treatment or placebo), patients were free to chose their further treatment for BPH. **RESULTS:** In all, 117 patients (59%) were eligible for analysis during the follow-up. Of the former beta-sitosterol group, 38 patients who continued beta-sitosterol treatment had stable values for all outcome variables between the end of the double-blind study and after 18 months of follow-up. The 41 patients choosing no further therapy had slightly worse symptom scores and PVR, but no changes in Q<sub>max</sub>. Of the former placebo group, 27 patients who started beta-sitosterol after the double-blind trial improved to the same extent as the treated group for all outcome variables. The 18 patients choosing no further therapy showed no signs of improvement. **CONCLUSION:** The beneficial effects of beta-sitosterol treatment recorded in the 6-month double-blind trial were maintained for 18 months. Further clinical trials should be conducted to confirm these results before concluding that phytotherapy with beta-sitosterol is effective.