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Clinical Trial

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Long-term efficacy and safety of a combination of sabal and urtica extract for lower urinary tract symptoms--a placebo-controlled, double-blind, multicenter trial

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Abstract

The efficacy and tolerability of a fixed combination of 160 mg sabal fruit extract WS 1473 and 120 mg urtica root extract WS 1031 per capsule (PRO 160/120) was investigated in elderly, male patients suffering from lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia in a prospective multicenter trial. A total of 257 patients (129 and 128, respectively) were randomized to treatment with PRO 160/120 or placebo (127 and 126 were evaluable for efficacy). Following a single-blind placebo run-in phase of 2 weeks, the patients received 2 x 1 capsule/day of the study medication under double-blind conditions over a period of 24 weeks. Double-blind treatment was followed by an open control period of 24 weeks during which all patients were administered PRO 160/120. Outcome measures for treatment efficacy included the assessment of the patients' LUTS by means of the I-PSS self-rating questionnaire and a quality of life index as well as uroflow and sonographic parameters. Using the International Prostate Symptom Score (I-PSS), patients treated with PRO 160/120 exhibited a substantially higher total score reduction after 24 weeks of double-blind treatment than patients of the placebo group (6 points vs 4 points; P=0.003, one tailed) with a tendency in the same direction after 16 weeks. This applied to obstructive as well as to irritative symptoms, and to patients with moderate or severe symptoms at baseline. Patients randomized to placebo showed a marked improvement in LUTS (as measured by the I-PSS) after being switched to PRO 160/120 during the control period (P=0.01, one tailed, in comparison to those who had been treated with PRO 160/120 in the double-blind phase). The tolerability of PRO 160/120 was comparable to the placebo. In conclusion, PRO 160/120 was clearly superior to the placebo for the amelioration of LUTS as measured by the I-PSS. PRO 160/120 is advantageous in obstructive and irritative urinary symptoms and in patients with moderate and severe symptoms. The tolerability of the herbal extract was excellent.

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