Clinical Studies on Saw Palmetto (*Serenoa repens* [W. Bartram] Small)

Benign Prostatic Hyperplasia (BPH)

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Ziegler and Holscher, 1998	BPH	O, MC n=109 men with BPH in Stages I and II	3 months	160 mg; 2x/day	Prostagutt® (WS 1473)	Saw palmetto caused a significant ($p<0.001$) improvement in subjective assessment. Therapy was well-tolerated. Significant improvement in mean flow rate ($p<0.0001$), micturition time ($p<0.0001$), and time to peak flow rate ($p<0.0001$) with intent-to-treat analysis. No significant change in micturition volume. Significant decrease in residual volume ($p<0.0001$), significant decline in daytime micturition ($p<0.0001$) and in nocturia ($p<0.0001$).
Redecker, 1998	BPH	O n=50 men with BPH in Stages I and II	3 months	160 mg; 2x/day	Prostagutt® (WS 1473)	Saw palmetto caused a significant increase in maximum urinary flow rate ($p<0.001$), a reduction in residual urine volume, and reduction of micturition frequency (26 ml to 15 ml).
Di Silverio, 1998	BPH	R, C n=25 men with BPH	3 months	160 mg; 2x/day or no treatment	Permixon®	Compared to control, those receiving saw palmetto had a significant reduction in prostatic DHT ($p<0.001$) and epidermal growth factor (EGF) ($p<0.01$). They had a significant increase in testosterone levels ($p<0.001$). Highest values were in peri-urethral area.
Braeckman, 1997	BPH	R, SB, PC, P MC n=132 men with BPH	1 year	160 mg; 2x/day, or 320 mg, 1x/day	Prostaserene®	Both doses of saw palmetto extract significantly improved International Prostate Symptom Score ($p<0.0001$), quality of life score ($p<0.0001$), prostatic volume ($p<0.0001$), maximum flow rate ($p<0.0001$), mean flow rate ($p<0.01$), and residual urinary volume. The two doses were not significantly different. The extract was found to be safe.
Bach and Ebeling, 1996	BPH	P, MC n=315 men with BPH Stage II or III	3 years	160 mg; 2x/day	Strogen® S (IDS 89)	For 80% of patients, clinical status and quality of life improved markedly. 50% of patients had an improvement in residual urine, flow time, and flow rate. Adverse side effects (e.g., gastrointestinal disturbances, urinary tract infections, ejaculation problems, impotence) were experienced by 2% of patients.
Kondás *et al.*, 1996	BPH	O n=38 men with moderate BPH Stages II–III (Vahlensieck)	12 months	320 mg/day	Strogen forte® (IDS 89)	Of patients participating, 74% had an improvement on International Prostate Symptom Score. Greatest improvement rates were noted for sensation of residue, interruption of micturition, and force of urinary stream. Subjective reports of improvement did not depend on size of hyperplastic prostate. Significant increase in average peak flow rate ($p<0.001$). Decrease in residual volume ($p<0.001$). Decrease in average volume of prostate ($p<0.02$). No adverse reactions.
Carraro, 1996	BPH	R, DB, C n=951 men with moderate BPH	6 months	160 mg, 2x/day Permixon® or 5 mg/day finasteride	Permixon® and finasteride	Both treatments equally decreased symptoms of BPH. Saw palmetto had minimal effect on prostate volume and no effect on PSA concentration. Saw palmetto was more effective than finasteride in reducing lower urinary tract symptoms in men with smaller prostate size. Significant results in favor of finasteride for urinary flow rate and prostate volume. Significant decrease in PSA levels with finasteride. Significantly more subjects withdrew from study with finasteride.
Braeckman, 1994	BPH	O, MC n=305 men with mild to moderate BPH	3 months	160 mg, 2x/day	Prostaserene®	After 45 days of treatment there was significant ($p<0.0001$) improvement in International Prostate Symptom Score, quality of life, urinary flow rate, residual urinary volume, and prostate size. Serum PSA concentration was not modified by saw palmetto extract, decreasing the risk of possible development of prostate cancer during treatment. Only 5% of patients reported side effects.

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Clinical Studies on Saw Palmetto (*Serenoa repens* [W. Bartram] Small) (cont.)

Benign Prostatic Hyperplasia (BPH) (cont.)

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Vahlensieck *et al*., 1993a	BPH	OB n=578 (BPH Stages II and III)	8 months; 12 weeks of treatment	160 mg, 2x/day	Talso®	Clear clinical improvements were seen in symptoms, including urine flow, urine retention, nocturia, and daytime micturition. The residue urine volume was reduced by approximately half after 12 weeks, with 30% reduction after 4 weeks. The physicians evaluated efficacy as good or very good in over 80% of the subjects with over 95% of the subjects demonstrating good or very good tolerability.
Vahlensieck *et al*., 1993b	BPH	OB n=1,334	8 months	160 mg, 2x/day	Talso®	The study was based on symptom treatment and patient evaluations. During the treatment period, pollakiuria was reduced by 37%, nocturia by 54%, and the volume of residual urine was reduced by 50%. The number of patients with dysuria was reduced from 75% to 37%. 80% of the patients rated good or very good efficacy at 80% and good or very good tolerability at 95%.
Casarosa, 1988	BPH	PC n=20 men with BPH and normal levels of testosterone, LH, and FSH. (50–70 years)	30 days	160 mg, 2x/day or placebo	LG 166/S	One month of treatment with saw palmetto extract did not alter testoterone, LH, or FSH levels. These findings are in contrast to those of Tenaglia and DiSilverio (1986) who found increases in the hormone levels. The authors have no explanation for the discrepancy.
Champault, 1984	BPH	R, PC n=110 men (ages 47–92), with BPH, not needing surgery	28 days	160 mg, 2x/day or placebo	Saw palmetto extract (PA 109)	Patients taking saw palmetto had significant decrease in nocturnal micturitions ($p<0.001$), dysuria (painful urination), and rate of micturition as compared to placebo. No adverse effects reported. Significant increase in urinary flow with saw palmetto extract ($p<0.001$).

Combination Preparations

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Marks *et al*., 2001	BPH	R, PC, Cm n=40 (saw palmetto vs. placebo), n=22 (finasteride vs. control), measuring prostate tissue androgen levels using needle biopsies	6 months	318 mg saw palmetto extract/day; 1 tablet, 3x/day with meals, or placebo	Nutrilite® Saw Palmetto with Nettle Root (containing saw palmetto extract 106 mg, nettle root extract 80 mg, lemon bioflavonoid extract 33 mg, and vitamin A, 190 IU)	In the saw palmetto group, tissue DHT levels were reduced by 32% from 6.49 ng/g to 4.40 ng/g ($p<0.005$). The effect of chronic finasteride therapy was statistically significant ($p<0.01$) in lowering prostate tissue DHT levels (80%) compared to levels of testosterone. No significant change in tissue DHT levels was observed with the placebo.
Marks *et al*., 2000	BPH	R, DB, PC n=41 men with symptomatic BPH. OL extension after 6 months	6 months	318 mg saw palmetto extract/day, 1 tablet, 3x/day with meals, or placebo	Nutrilite® Saw Palmetto with Nettle Root (containing saw palmetto extract 106 mg, nettle root extract 80 mg, lemon bioflavonoid extract 33 mg, and vitamin A, 190 IU)	Saw palmetto blend group had non-statistically significant improvement vs. placebo in clinical parameters (e.g., International Prostate Symptom Score, uroflowmetry, residual urine volume, prostate volume). After 6 months, saw palmetto blend was associated with prostate epithelial contraction, notably in transition zone ($p<0.01$), suggesting possible mechanism for clinical significance found by other studies. No serious adverse effects were associated with saw palmetto blend.

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Benign Prostatic Hyperplasia (BPH)

Combination Preparations (cont.)

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Sökeland, 2000	BPH	R, MC, DB n=431	48 weeks	2 capsules PRO 160/120®/day vs. finasteride (5 mg/day) vs. placebo	PRO 160/120® (Prostagutt forte™, fixed combination of 160 mg of saw palmetto extract [WS 1473] and 120 mg of stinging nettle dry extract [WS 1031]) or finasteride	The efficacy of both PRO 160/120® and finasteride were shown to be equivalent in the International Prostate Symptom Score with tolerability significantly better with PRO 160/120®. 96 adverse events were recorded in 54 patients using finasteride compared with 74 in 52 patients taking PRO 160/120®.
Sökeland and Albrecht, 1997	BPH (Stages I and II)	R, RC, MC, DB, PG n=543	48 weeks	2 capsules PRO 160/120®/day vs. finasteride (5 mg/day) vs. placebo or one capsule of 5 mg of finasteride per day	PRO 160/120® (Prostagutt forte™, fixed combination of 160 mg of saw palmetto extract [WS 1473] and 120 mg of stinging nettle dry extract [WS 1031]) or finasteride	International-Prostate-Symptom-Score (I-PSS) value improved by a total of 4.8 points with the PRO 160/120®. The study found equivalent efficacy between the two groups. Less adverse events, including diminished ejaculation volume, erectile dysfunction and headache, were reported in the PRO 160/120® group. The study recommended that patients should receive finasteride only after the use of the combination for at least 3 months was unsuccessful.
Metzker *et al.*, 1996	BPH (Stages I and II)	DB, PC n=40	350 days	2 capsules PRO 160/120®/day vs. finasteride (5 mg/day) vs. placebo	Prostagutt forte™ (fixed combination of 160 mg of saw palmetto extract [WS 1473] and 120 mg of stinging nettle dry extract [WS 1031])	The study concluded good efficacy and tolerance in the administration of PRO 160/120® for approximately one year of therapy. After 24 weeks, maximum urine volume per second by 3.3 ml/s had occurred with the combination compared to only a slight improvement of 0.55 ml/s with placebo. Subjective reports corresponding to the I-PSS found a highly significant ($p<0.001$) advantage with the combination vs. placebo.
Schneider *et al.*, 1995	BPH (Stages I and II)	S n=2,080	12 weeks	2 capsules PRO 160/120®/day vs. finasteride (5 mg/day) vs. placebo	Prostagutt forte™ (fixed combination of 160 mg of saw palmetto extract [WS 1473] and 120 mg of stinging nettle dry extract [WS 1031])	Treatment with the combination was found to be an effective method to avoid surgery or not to make it necessary as soon. Physician and patient assessment confirmed the efficacy and tolerance of PRO 160/120®.

Lower Urinary Tract Symptoms

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Gerber *et al.*, 1998	Lower urinary tract symptoms	O n=46 men with lower urinary tract symptoms secondary to BPH	6 months	160 mg, 2x/day	Solaray® Saw Palmetto	The International Prostate Symptom Score significantly improved ($p<0.001$) after 2 months of treatment. No significant change in peak urinary flow rate, post void residual urine volume, or detrusor pressure at peak flow. No significant improvement in objective measures of bladder outlet obstruction. Saw palmetto was well-tolerated.

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