Clinical Studies on Prostagutt® forte

Benign Prostatic Hyperplasia (BPH)

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Sökeland, 2000 (Also published as Sökeland and Albrecht, 1997)	BPH (stages I and II)	R, RC, MC, DB, PG n=543	48 weeks	2 capsules per day	PRO 160/120 (Prostagutt® forte) or finasteride (Proscar®)	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 2 groups. The therapeutic outcome was unrelated to the prostate volume in either treatment group. 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	24 weeks, followed by 24 weeks single blind phase	2 capsules per day	PRO 160/120 (Prostagutt® forte)	The study concluded good efficacy and tolerance in the administration of PRO 160/120 for approximately 1 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)	O, MC, P, OB n=2,080	12 weeks	2 capsules per day	PRO 160/120 (Prostagutt® forte	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. Side effects (mild gastrointestinal complaints) were observed in only 0.7% of patients.

KEY: **C** – controlled, **CC** – case-control, **CH** – cohort, **CI** – confidence interval, **Cm** – comparison, **CO** – crossover, **CS** – cross-sectional, **DB** – double-blind, **E** – epidemiological, **LC** – longitudinal cohort, **MA** – meta-analysis, **MC** – multi-center, **n** – number of patients, **O** – open, **OB** – observational, **OL** – open label, **OR** – odds ratio, **P** – prospective, **PB** – patient-blind, **PC** – placebo-controlled, **PG** – parallel group, **PS** – pilot study, **R** – randomized, **RC** – reference-controlled, **RCS** – retrospective cross-sectional, **RS** - retrospective, **S** – surveillance, **SB** – single-blind, **SC** – single-center, **U** – uncontrolled, **UP** – unpublished, **VC** – vehicle-controlled.