

**[Clinical evaluation of Cernilton on benign prostatic hypertrophy--a multiple center double-blind study with Paraprost]**

[Article in Japanese]

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A multiple center double blind study was performed to study the effectiveness of Cernilton (CN) on benign prostatic hypertrophy in comparison to Paraprost (PP). Among a total of 192 patients, overall effect was studied on 159 patients, overall safety rate on 178 patients and rate of effectiveness on 159 patients. There were no differences between the two groups in the selected patients, criteria for exclusion and drop out cases or background data of the patients. Impression of patients and overall effect by committee and physician judgment were slightly higher in the CN group compared to the PP group, but there was no significant difference between the two groups. For the improvement in subjective symptoms, the rate of moderate improvement or more after 4 weeks by committee judgement was higher in the CN group compared to the PP group. The rate of improvement in protracted miction, which is an effective marker of urinary disturbance, was also higher in the CN group compared to the PP group. An analysis of objective symptoms showed a significant improvement in residual urinary volume, average flow rate, maximum flow rate and prostatic weight in the CN group. A significant improvement in the phased change of residual urinary volume was also seen in the CN group. No side effects or abnormalities in clinical test levels were noted in the CN group. By committee judgement, the rate of more than moderate effectiveness was 49.1% in the CN group compared to 41.2% in the PP group, but there was no significant difference between the two groups. By physician's judgment, the rate of more than moderate effectiveness was 49.4% in the CN group compared to 46.3% in the PP group, but there was also no significant difference between the two groups. These results suggested that Cernilton was an effective drug for benign prostatic hypertrophy.