Research Abstracts

Flower Pollen Extract

Clinical evaluation of long-term treatment using cernitin pollen extract in patients with benign prostatic hyperplasia

Seventy-nine patients with benign prostatic hyperplasia (BPH) were treated with cernitin pollen extract. Patient ages ranged from 62 to 89 years (mean, 68 years). Mean baseline prostatic volume was 33.2 cm3. Cernitin pollen extract was administered in a dosage of 126 mg (2 tablets, 63 mg each), three times a day, for more than 12 weeks. Symptom scores, based on a modified Boyarsky scoring scale, uroflowmetry, prostatic volume, residual urine volume, and urinalysis results were examined before and after administration of cernitin pollen extract. Symptom scores significantly decreased from baseline, and the favorable results continued during the treatment period. Urine maximum flow rate and average flow rate increased significantly from 9.3 mL/s to 11 mL/s and from 5.1 mL/s to 6 mL/s, respectively. Residual urine volume decreased significantly from 54.2 mL to less than 30 mL. There was no change in prostatic volume. However, 28 patients treated for more than 1 year showed a mean decrease of prostatic volume to 26.5 cm3. No adverse reactions were observed. Clinical efficacy at 12 weeks was rated excellent, good, satisfactory, and poor in 11%, 39%, 35%, and 15% of patients, respectively. Overall clinical efficacy was 85%. In conclusion, cernitin pollen extract showed a mild beneficial effect on prostatic volume and urination variables in patients with symptomatic BPH. Yasumoto R et al. *Clin Ther* 1995 Jan-Feb;17(1):82-7.

Results of treatment with pollen extract (Cernilton N) in chronic prostatitis and prostatodynia

We report the results of a prospective study with the pollen extract, Cernilton N, in a dose of 1 tablet tid for 6 months for the treatment of chronic prostatitis syndrome in 90 patients. The factors documented before and after 3 and 6 months' treatment were digital rectal examination (DRE) of the prostate, uroflowmetry, bacterial studies, leucocyte counts in urine and measurement of complement C3/coeruloplasmin in the seminal fluid. The patients were divided into 2 groups: those without associated complicating factors (CFs) (n = 72) and those with complicating factors, i.e. urethral strictures, prostatic calculi, bladder neck sclerosis (n = 18). In the group without CFs, 56 (78%) had a favorable response; 26 (36%) were cured of their symptoms and signs and 30 (42%) improved significantly with an increase in flow rate, a reduction in leukocyturia in the post-prostate massage urine (VB3) and a decrease in complement C3/coeruloplasmin in the ejaculate. In the patients with CFs only 1 patient showed a response. Complicating factors should be considered in patients who fail to respond to treatment within 3 months. Cernilton N was well tolerated by 97% of patients. Rugendorff EW, Weidner W, Ebeling L, Buck AC. *Br J Urol* 1993 Apr;71(4):433-8.

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

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. Maekawa M et al. *Hinyokika Kiyo* 1990 Apr;36(4):495-516.

Treatment of outflow tract obstruction due to benign prostatic hyperplasia with the pollen extract, cernilton. A double-blind, placebo-controlled study

Whilst prostatectomy remains the "gold standard" for the treatment of outflow tract obstruction due to benign prostatic hyperplasia, medical treatment--if only for symptomatic relief--appears to be an attractive alternative. Most of the pharmacological agents in use block the hormonal or the sympathetic neurological pathways that influence prostate growth and function. All of these drugs are known to have side effects. Sixty patients with outflow obstruction due to benign prostatic hyperplasia (BPH) were entered into a double-blind, placebo-controlled study to evaluate the effect of a 6-month course of the pollen extract, Cernilton. There was a statistically significant subjective improvement with Cernilton (69% of the patients) compared with placebo (30%). There was a significant decrease in residual urine in the patients treated with Cernilton and in the antero-posterior (A-P) diameter of the prostate on ultrasound. However, differences in respect of flow rate and voided volume were not statistically significant. It is concluded that Cernilton has a beneficial effect in BPH and may have a place in the treatment of patients with mild or moderate symptoms of outflow obstruction. Buck AC, Cox R, Rees RW, Ebeling L, John A. *Br J Urol* 1990 Oct;66(4):398-404.

A long-term therapeutic experience with Cernilton in chronic prostatitis

Thirty-two patients with chronic prostatitis were given 6 tablets of Cernilton daily for 12.6 weeks on the average. Improvement of subjective symptoms and objective findings was noted in 74.2% and 65.6% of the cases, respectively. The effective rate was 75.0%. No subjective symptoms or abnormal changes in laboratory data were observed in any case after Cernilton medication. Hinyokika Kiyo 1988 Mar;34(3):561-8. Jodai A, Maruta N, Shimomae E, Sakuragi T, Shindo K, Saito Y. *Hinyokika Kiyo* 1988 Mar;34(3):561-8.

Clinical evaluation of cernilton in the treatment of the benign prostatic hypertrophy

Cernilton was given clinically to 30 patients with benign prostatic hypertrophy. Cernilton was given orally at least for 12 weeks at a daily dose of 6 tablets in three divided doses. The overall clinical efficacy on subjective symptoms was 80%, and that on objective signs, 43%. During the administration period of Cernilton, no serious untoward effects were observed in either the clinical or laboratory findings. It is, therefore, suggested that, from the clinical point of view, Cernilton is a useful and safe drug in the treatment of benign prostatic hypertrophy. Horii A, Iwai S, Maekawa M, Tsujita M. *Hinyokika Kiyo* 1985 Apr;31(4):739-46.

Treatment of chronic prostatitis and prostatodynia with pollen extract

Chronic abacterial prostatitis and prostatodynia are notoriously difficult both to diagnose and to treat. These patients tend to have received several courses of antibiotics, antiinflammatory agents or adrenergic blockade and various other therapeutic manoeuvres with little success. The pollen extract, Cernilton, is reported to be effective in the treatment of this condition and we present the results of an open trial with Cernilton in a group of 15 patients with chronic prostatitis and prostatodynia. In 13 patients there was either complete and lasting relief of symptoms or a marked improvement; 2 patients failed to respond. Cernilton was found to be effective in the treatment of chronic prostatitis and prostatodynia. Its precise mode of action is not known, although experimental studies suggest that it has anti inflammatory and anti-androgenic properties. Buck AC, Rees RW, Ebeling L. *Br J Urol* 1989 Nov;64(5):496-9.

In vitro evaluation of the pollen extract, cernitin T-60, in the regulation of prostate cell growth

Nine human-derived cancer and non-cancer continuous cell lines were employed to evaluate the relative in vitro activity of the pollen extract, Cernitin T-60. Responses of the cell lines to the drug were assessed by measuring growth and cell survival as determined by cell count. The results demonstrated that of the 9 continuous cell lines tested, only those derived from the human prostate were growth inhibited by the pollen extract, whereas the non-prostate derived cells exhibited variable degrees of resistance to the T-60. The selectivity of the drug for the prostate cell lines was even more pronounced in the hormone-independent models, suggesting that there might be a place for the pollen extract in the control of abnormal growth in hormone-insensitive cells. Habib FK, Ross M, Buck AC, Ebeling L, Lewenstein A. *Br J Uro*l 1990 Oct;66(4):393-7.

Inhibition of arachidonic acid cascade by extract of rye pollen

A standardized extract mainly from rye pollen (Cernilton N) was tested in vitro on the inhibition of prostaglandin and leukotrien synthesis. The determination of the prostaglandin and leukotrien synthesis from labelled arachidonic acid was done in microsomes of ram seminal vesicles resp. in rat basophilic leukemia cells (RBL-1 cells). The water soluble resp. the fat soluble extract fraction from the whole pollen extract were tested separately. The radio-TLC separation of the reaction metabolites showed a dose dependent inhibition of the cyclo-oxygenase and the 5-lipoxygenase activity by the fat soluble pollen extract fraction. The IC50-values are 0.005 mg/ml resp. 0.08 mg/ml and similar to those of the also tested diclofenac. The water soluble fractions showed no effect in this test system. According to these in vitro results and the clinical experience sofar with the pollen extract its therapeutic efficacy on benign prostate diseases is best explainable by the anticongestive resp. anti-inflammatory effect of the fat soluble fraction. Due to the different actions of prostaglandins and leucotrienes also relaxant and antiproliferative effects were conceivable. Loschen G, Ebeling L. *Arzneimittelforschung* 1991 Feb;41(2):162-7.

Inhibitory effect and synergism of cernitin pollen extract on the urethral smooth muscle and diaphragm of the rat

Inhibitory effects of cernitin pollen extract (CN-009), consisting of T-60 (a water-soluble extract) and GBX (an acetone-soluble extract) at a ratio of 20:1, were investigated in rat urethral smooth muscle and diaphragm. In the urethralsmooth muscle, CN-009 (3.0 x 10(-4) approximately 3.0 x 10(-3) g/ml), T-60 and GBX (corresponding to CN-009) concentration-dependently inhibited the noradrenaline (NA, 10(-5) g/ml)-induced contraction. According to Burgi's calculation, the inhibition by T-60 and GBX was synergistic. On the other hand, GBX inhibited the NA-contraction non-competitively and also inhibited the K+-contraction. In contrast, T-60 tended to inhibit competitively, but did not affect the K+-contraction. In the diaphragm, CN-009 (5.25 x 10(-3) approximately 2.1 x 10(-2) g/ml) concentration-dependently inhibited the nerve stimulation-induced twitch response. T-60 (corresponding to CN-009) showed no effect, while GBX slightly inhibited the twitch response. The effects of T-60 and GBX were synergistic. The inhibitory effects of CN-009 (2.1 x 10(-2) g/ml) and GBX (1.0 x 10(-2) g/ml) were specific against the nerve stimulation and were not antagonized by neostigmine (1.0 x 10(-5) g/ml). These results suggested that these effects were neither musculotropic nor competitive against ACh. In conclusion, CN-009 concentration-dependently inhibited the urethral contraction and the skeletal muscular twitch response. It was suggested that T-60 and GBX had different mechanisms and inhibited the response synergistically. Nakase K, Takenaga K, Hamanaka T, Kimura M. *Nippon Yakurigaku Zasshi* 1988 Jun;91(6):385-92.