The Effect of Cernitin on Upper Respiratory Tract Infections

Jon Glomme, M.D.

University Health Service, University of Oslo, Blindern, Oslo 3, Norway

October 21st, 1973

A number of reports have given as the definite opinion of a number of well-known urologists that the carefully digested pollen extract called Cernitin, constituting the active principle in “Cernitin”, has a good effect on chronic prostatitis when the definitions (1,2,3) and the indications are made clear (4,5,2,6).

There are also a number of reports stating that Cernilton has beneficial effect upon infections in the upper respiratory tract (7,8,9,10).

Experimentally a great number of investigations have shown that Cernilton is practically non-toxic (11,12,13). It has also been proved that there is a streptolysing inhibitory factor in Cernilton T 60 which is the main constituent of Cernilton (14, 15).

In animal experiments a statistically probable significant effect of Cernilton on the frequency of spontaneous lung infects in rats (17) may be present.

The above mentioned results, especially when having a certain support in well-controlled animal experiments, made it natural to go more detailed into the problems as to the possible anti-infectious effect of Cernilton regarding the upper respiratory tract. This problem was studied in some detail by Malstrom and Cederlof (7) when administering in a double-blind experiment Cernilton and placebo respectively to a fairly great number of military personnel. This type of clinical trials have many definite advantages especially for double-blind studies: the examined persons are of the same sex and age and are generally speaking under the same influence by the surroundings and the climate and they may be looked upon as randomized selection as to motivation. This should therefore a priori be acceptable as a group well suited for comparison. In the report of Malstrom and Cederlof (1966-1967) (7) there is some striking features. In total there were 615 observed military persons. The Cernilton and placebos respectively which were identical as to taste and appearance, there was by the dechiffration proved to be 294 who had got the placebos and 321 who had got Cernilton. The distribution was made in a way which gave very good randomizing of the distribution within every small group and section which made it highly improbable that there should be any significant difference because of the distribution of the preparations used.

The most striking features is the results as to the number of persons during the 14 days of observation where all the preparations used when regarding the number of sick absences and the number of visiting doctors for upper respiratory tract troubles.

Among the 294 men in the placebo-treated group 17 were visiting the doctor for upper respiratory tract diseases. This makes 5.8 percent ± 1.39. In the Cernilton-treated group there were only 8 visits to the doctor because of upper respiratory tract diseases that makes 2.5 percent ± 0.87. The difference as to visiting the doctors because of upper respiratory tract diseases is 3.3 percent ± 1.64. This gives a t-value (according to Students-t-test) = 2.01 and a

probability of statistical significance on the 5 percent level.

As to the frequency of sick-leave this occurred in the placebo-treated group in 26 cases (among the 294 persons) which makes 8.8 percent ± 1.67. In the Cernilton-treated group there were altogether 11 cases of sick-leave among the 321 men, which makes 3.4 percent ± 1.01. This gives a difference between placebo-treated group and the Cernilton-treated group on 5.4 ± 1.95. According to Students-t-test this gives a t-value of 2.77 and a statistical significant difference on the 1 per cent level (0.01>p>0.001).

As to the single symptoms treated within each of the 4 different groups separately, there is a difference as to the frequency of sore throat on the 2 percent level in 2 out of the 4 groups in favor of Cernilton. It is also a difference as to the frequency of coughing between Cernilton and the placebo-treated groups in 2 of the separated divisions on respectively the 10 percent level and the 5 percent level. As to the rhinitis symptoms there is no certain difference of trend in any of the groups. The trend in the results of the enquete gives partly 10 percent partly 20 percent significance in favor of the Cernilton group generally speaking when regarding most of the symptoms from the upper respiratory tract but no definite or probable statistical significance except for the symptoms in the few groups mentioned above.

Even more interesting when regarding the generally roborating effect, which has been presumed for Cernilton, is the results given by the 615 men as to their general condition and feeling of well-being. It is as to these subjective symptoms a difference on the 10 percent level in favor of Cernilton as the total groups are regarded and when regarding only about 40 percent which have had any symptoms or signs indicating an upper respiratory tract disease, it is significant difference on the 2.5 per cent level in favor of the Cernilton-treated group compared with the placebo-treated group.

As this report has never been published it has been found of interest to give a fairly extensive extract of the results.

Dr. med. H. Klapsch (8) has in his report as to the effect of the “Grippen-Tabletten Fluaxin” stated that this tablet which contains a small amount of acetylsalicylic acid together with the pollen extract, was given as prophylacticum or as therapy to people occupied in a heavy industry where he was the industrial physician when the actual candidates had a feeling of getting sick in influenza or upper respiratory tract infections.

Altogether the tablets were given to 510 persons. In addition to the about 52 percent of the total number of employees who got the Cernilton-containing tablet there was 5.5 percent getting another so called “Grippen-Tableitte A” and 6.3 percent another type of so called “Grippen-Tablette B”.

It may be of some interest to give a few of the observations reported by Dr. H. Klapsch. Of the 510 (52 percent) who got the Cernitin-containing tablets, 6 (2.4 percent) who got the tablets only once (6 tablets specially prepared) got an upper respiratory tract infection which caused sick-leave. Among those who asked for the tablets only 1.1 percent had a sick-leave because of an upper respiratory disease during the period of observation.

The total frequency of sick-leave because of upper respiratory tract infections thus was about the same in the group which got the Cernitin-contained tablets as in the group getting one of the two other tablets which should serve the same purpose about: a total of about 2 percent sick-leave because of “Grippe” or upper respiratory tract diseases.

The fairly small difference between sick-absence: 2.4 percent and 1.1 percent respectively gives a t-value according to Students-t-test on 1.20 which is not statistically significant (0.3>p>0.2).

Only among a few of the patients getting the Cernitin-containing tablets Dr. Klapsch ask about the patients' reactions and in those cases about 8 percent gave a good or very good effect as about 14 persons gave a bad effect.

Altogether 7 patients (1.4 per cent) gave side effects as cephalalgia, extreme tiredness, feeling of being unwell and sweating. As there are given as the only spontaneous side-effects and all belong to most of the upper respiratory tract infections there does not seem to be any real side effect of the tablets as reported by Dr. Klapsch.

Although Dr. Klapsch himself is drawing the conclusion that there is a very good effect of the Cernitin-containing Fluaxin tablets as prophylacticum and therapeutics against upper respiratory tract disease and/or "influenza" there is no definite evidence in his report which supports his opinion.

As to the investigation of Lindberg and Sorensen (1968) (8) "A tentative treatment of the common cold with Cernitin", this is carried out as "prophylactic" treatment when the first symptoms of a common cold was observed by the test persons themselves. All the patients were treated according to double-blind controlled clinical trial technique. All of them got 30 tablets of which they should take 10 immediately as soon as they observed any symptoms or signs of a beginning common cold, then 10 tablets again after 8-12 hours and finally 10 tablets again after another 8-12 hours. Further supply of tablets could then be given by the physician in charge of trial. Neither the physicians not the patients knew anything about the type of tablets besides that they were quite harmless and contained vitamins, minerals and amino acids and other quite harmless substances. After dchiffation of the test it turned out that in the Cernitin-treated group there were 83 percent who have given that they were either completely free from symptoms within the first day or that the symptoms of the common cold or upper respiratory tract disease lasted for a shorter period and the symptoms were less severe than usual. Only 17 percent hold the opinion they could not observe any effect at all. In the control group which had got placebos, there were 63 percent who gave that they're signs and symptoms disappeared completely within the first day or that the signs and symptoms were easier or had a shorter duration than usual. The Cernilton=treated group proved to consist of 39 persons while the control group consisted of 24 persons. (If treating these results statistically the author got the following table:

Table 1.

Subjective estimate of symptoms of common cold or from the upper respiratory tract in Cernilton-treated and placebo-treated groups.

Subjective estimate of symptoms	Cernilton-treated group		Control-group (placebo-group)	
	No.	Per cent	No.	Per cent
Symptoms disappeared completely within 1 day	13	45	8	33
Symptoms disappeared more rapid or were easier than usual	11	38	7	30
No effect at all	5	17	9	37
Total	29	100	24	100

It is obvious that we have a fairly high frequency of "placebo-effect" in both groups. If trying to find out whether there is a real difference between the groups it may be reasonable to treat together the groups which found that their symptoms and signs disappeared completely within one day and the group which found their symptoms and signs were easier or of shorter duration.

Table 2

Subjective estimate of symptoms	Cernilton-treated group		Control-group (placebo-group)	
	No.	Per cent	No.	Per cent
Definite improvement of signs and symptoms	24	83	15	63
No effect	5	17	9	37
Total	29	100	24	100

This makes a difference in favour of the Cernilton-treated groups fo 83 per cent $\pm$ 7.1 against 63 per cent $\pm$ 10.1.

The difference is 20 per cent $\pm$ 12.3 which according to Student-t-test gives a t-value on 1.63 and a probability of $0.2 > P > 0.1$. This does not give a significant difference.

In 1970 and 1972 Glømme has carried through a systematic clinical trial of Cernilton in cases which are bordered by infections as continuous or very often occurring recidives of sore throat or what they may call common cold. Most of these patients are known by the author from before and many of them have been interested in trying vaccination with standard-vaccine or auto vaccine to try to get rid of their troubles from the upper respiratory tract. Altogether these tests have been carried out as a prophylactic treatment in 180 cases and lasted 4 months. The patients in these controlled trials were all given medication according to the double-blind technique and the dechiffration was carried out unknown to the author who was treating the patients. Seventy nine percent did return and satisfied the requirements of the total examination. Sixty six (47%) belonged to the placebo-group. The difference in favor of Cernilton of 52 percent compared with 45 percent gives a t-value of 1.71 and (according to the students-t-test) and is significant on the 10 percent level that this difference may not only be occurring by chance.

In these cases there are carried out very careful clinical- and laboratory investigations which also include measuring of heights and weight (some of the patients are claiming that the appetite increases when using the preparations) sedimentation rate, hemoglobin amount, iron in serum, transferrin, cholesterol, electrocardiogram as to state as far as possible the normal condition of the heart, bacteriological examination from the nose and throat and examination as to the antistreptolysintiter. As to all these parameters these is no difference between the groups.

The four investigations referred to cannot be dealt with combined.

They are all aiming at somewhat different approaches. Malstrom and Cederlof have carried through a prophylactic treatment in a not definitely stated period of time and Lindberg has treated his patients at the onset of a common cold with a very high dosage but during a very short period of time. Glomme in contrast to the three others has, in his report, carried through a long-term prophylactic treatment on clinically very carefully examined patients who have been troubled in the past by upper respiratory tract diseases, more or less chronically or with frequent recidives. Therefore it is impossible to get a common statistical view on the possible effect of Cernilton on upper respiratory tract diseases by combining results from these four papers. It seems, a difference in favor of the Cernilton-treated groups in all of these papers but the difference is not great enough to make it statistically reliable or statistically significant.

On the other hand, as to frequency in sick-leave and visits to the doctor for upper respiratory tract diseases and even to general well-being and less pronounced symptoms with shorter duration in the paper reported by Malstrom and Cederlof statistical significant difference has been established.

However, these results seem so interesting that it must be worth-while to carry through careful and sufficiently extensive controlled clinical trials to try to find out whether there exists proved positive effect of Cernilton in cases of upper respiratory tract diseases. The results higher to

reported seem to tally fairly well with the opinion given by the author in connection with the experimental investigation on the effect of Cernilton on spontaneous lung infections in rats: that the most reasonable explanation may be that Cernilton gives a general roborating effect which may support the organism in its own resistance against infections. There is no indication that there are any definite and specific effects.

References

1. Romanus, R: Nordisk Medicine 7, 111. (1952). Chronic prostatovesiculitis.
2. Jonsson, G.: Svenska Läkartindningen (Swedish Medical Journal) 53 (1961) 2497. Prosatitis and Pollen.
3. Schnierstien, J.: Der Urologe 3:4 (1964) 202-208. Zur Termiologie der sogenannten chronischen Prostatitis.
4. Ask-Upmark, E.: Acta Medica Scand. 181 (1967) 355-357. Prostatitis and its treatment.
5. Alken, C.E., Röhl, L. And Jönsson, G: Unpublished report 1966. Report on a clinical trial of Cernilton in chronic prostatitis.
6. Heise, G.W.: Urologischen Klinik der Medizinischen Akademie, Magdeburg. 24.11.1970. Die Chronische Unspezifische Prostatitis.
7. Malstrom,S. And Cederlof, R.: Report 1965-1966. Om pollen som forkyl-ningsprrofylaktikum. (Pollen as a prophylactic against the common cold).
8. Klapsch, H.: From the Department of Industrial Medicine of a heavy Industry Concern, 1967. Experiences of Fluaxin, an anti-influenza medicine in tablet form.
9. Linderberg, E. and Sorensen, S.: A tentative treatment of the common cold with Cernilton. 1968.
10. Glomme, J: University Health Service, University of Oslo, Norway. Unpublished report. 1971. The effect of Cernilton on upper respiratory tract infections.
11. Magnusson, T. and Carlsson A.: Unpublished report, 1960. Report of experiments concerning the toxicity of the pollen preparations Cernitin D 30 UK and GBX-comp.
12. Nilsson, A and Jarplid, B.: Unpublished report. A summarized report of the results of pathological-anatomical studies of mice during long-term trials with Cernilton
13. Huntington Research Centre: Acute oral toxicity to mice. 1970.
14. 13b. Huntington Research Centre: Acute oral toxicity to rats. 1970.
15. Kienholz, M.: Municipal Hospital Offenbach a.M. Central Laboratory and Department for Medical Examinations, 1967. Streptolysin inactivating effect in Cernitin T 60.
16. Kvanta, E.: Institute of Chemistry, Teknikum, Vaxjo, Sweden. 1970. Stretolysin Inhibitory Factor in Pollen, (in press).
17. Karkkula, H.: Cernelle Symposium, 1963, pp. 28.
18. Glomme, J.: University Health Service, University of Oslo, Norway. Unpublished report 1971, 1973. A study on the effect of digested pollen extract on the frequency of spontaneous lung infections in rats.