COLD SYMPTOM SUPPORT:

GRAMINEX Flower Pollen Extract

Pollen as a Prophylactic against the Common Cold

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Pollen extract has been employed to a considerable extent, since 1955, in the treatment of prostate problems of various kinds (1-5, 8-11).

There would appear to be a widespread opinion that pollen extract also possesses a certain value as a roborant and cold-preventative. This effect has been referred to by Noyes [12] on the basis of a small amount of research material. The roborant effect has also been studied by Glömme [6] in comprehensive experiments on animals.

Critical epidemiological investigations on a large scale have not, however, been carried out. Against this background it seemed desirable to conduct a major field study of the effect of pollen extract on those liable to military service, in connection both with prevention of colds and with general roborant properties.

MATERIALS AND METHODS

The investigation was initiated by the Defense Department Research Institute, and carried out with the consent of the Military Governor in the Sixth Military Area (Upper Norrland), the Chief Physician to the Army, and the State Pharmaceutical Laboratory. The study was carried out on three separate occasions on a total of 775 conscripts in the Sixth Military Region. The designation and size of the groups studied are shown in Table 1.

Table 1. Group division and number of experimental persons

Group	Unit	Number of experimental persons
A	Eng. 3	224
B	Eng. 3	116
C	A 8	99
D	A 8	140
E	Eng. 3 rep-unit	44
F	Eng. 3	152

Group A consisted of newly enrolled conscripts, who were confined to barracks during the whole test period. The object of this was to test the problem during a period in which conscripts, who often come from different environments and different infective situations, are known from experience to be affected by a large number of mixed infections. With regard to Groups B-F, the experiments were carried out in connection with winter field-exercises, under conditions where troops are often exposed to major physical and psychical strains in a period when the danger of infection is great. In other particulars the experiments were carried out on all the field-service groups under substantially identical conditions.

The preparation to be tested, Cernilton, was made available by the manufacturers, AB Cernelle of Vegeholm. The dosage in group A, B and C was one tablet three times daily for 14 days. Two tablets were administered once daily for the same period to subjects of group E and F. The specifications of the preparations tested are shown in Table 2.

Table 2. The specifications of the preparations tested

Specification	Groups	
	A - C	E - F
Cernitin T60 sec. (Extr. pollinis aquos sec.)	60 mg	200 mg
Cernitin GBX$_t$ (Extr. pollinis oleos.)	3 mg	10 mg
Constituentiae et coloris	q. s.	q. s.
M.F. tabl. No. 1		

The experimental model was of the so-called double-blind type. Each unit was divided up into more-or-less equal ,,primar'' research units of 10 - 15 men, generally consisting of personel belonging to the same barrack-room, of smaller working group, with high individual working frequency. With the change distribution of the tablets it was ensured that every ,,primary unit'' was represented by more-or-less an equal number of experimental persons, with Cernilton or placebo-medication. This arrangement was made in order to balance any effect which might arise between the experimental persons within the various ,,primary units'' (infected). The blind tablets and Cernilton tablets had exactly the same taste and appearance.

A leader was selected for each group, whose responsibility it was to see to it that the tablets were taken in the way arranged. The experimental persons were asked to make notes on a special diary card during the whole experimental period concerning their state of health, with special attention to certain subjective symptoms, visits to the doctor, and sickness certification. The group leader was responsible for seeing that this was thoroughly carried out. No doctor participated in this part of the experiment.

RESULTS

The possible prophylactic effect of a preparation against symptoms of the common cold can obviously only be evaluated on the basis of material where there is ,,normally'' a rather high incidence of sickness. Of the six units tested during the relevant experimental periods, symptoms indicative of infection of the upper air passage occurred as indicated in Table 3. The table shows that the frequency of colds was low or very low in groups B and E. These groups have therefore been excluded from following discussion. The incidence of certain symptoms of infection of the upper air passage, divided up in accordance with the investigation group and type of tablet, is shown in Table 4.

Table 4. Incidence of sore throat, coughing, hoarseness, and nasal catarrh within the experimental groups

Symptom	Experimental groups							
	A		C		D		F	
	P	C	P	C	P	C	P	C
Sore throat	21,4	18,8	23,6	12,5	17,3	9,8	17,9	21,2
Coughing	28,0	30,7	35,3	29,2	18,8	11,2	31,3	21,2
Hoarseness	11,1	14,5	11,8	20,9	13,0	7,0	13,5	10,6
Nasal catarrh	37,5	35,0	31,4	29,3	24,6	28,2	32,9	31,7
Basic number	107	117	51	48	69	71	67	85

P – placebo (%), C – Cernilton (%)

The table shows a clear distinction between Cernilton and placebo treated experimental persons in investigation groups C and D in relation to sore throat. The differences are in favour of the preparation, and are significant at the 10% level, Khisquare analysis with correlation for continuity in the present case. Coughing also tends to occur rather less frequently with the Cernilton-treated groups (C, D, and F), though it is only within group F that the results are significant at the 10% level. The figures shown in the table for hoarseness and nasal catarrh symptoms can not be regarded as showing any effect: the difference between Cernilton-series and placebo-series are not significantly different from zero. Symptoms of influenza occurred only to a slight extent, and could not be used to evaluate any possible prophylactic effect.

The relative numbers of persons during the observation period who visited the doctor or were certified sick are shown in Table 5.
Visits to the doctor and sick-certification occurred practically only in groups D and F. There was a clear distinction favourable to the preparation between the Cernilton and placebo treated experimental persons, particularly in group D, but also to some extent in group F. The distinction for group D is significant at the 5% level with respect to visits to the doctor, and at the 1% level with respect to sick-certification.

Table 5. Visits to the doctor and sickness certification within the experimental groups

Visits	Experimental groups							
	A		C		D		F	
	P	C	P	C	P	C	P	C
Visited doctor	0,9	0,0	3,9	4,2	13,0	2,8	7,5	4,7
Certified sick	2,8	0,0	0,0	0,0	17,3	2,8	16,5	10,7
Basic number	107	117	51	48	69	71	67	85

P – placebo (%), C – Cernilton (%)

With respect to all the symptoms discussed here, and also to sick-certification, the experimental persons were asked to indicate for how long the symptoms or the certification had lasted. There was no clear distinction between Cernilton-treated and placebo-treated individuals, although there was a certain non-significant tendency for shorter times observed in the case of the Cernilton groups.

The experimental persons were also asked to give a general opinion about their condition during the experimental period, in particular as to whether they felt more tired or more alertt than usual. The alternative answers were formulated differently in the 1965 and 1966 investigations. In 1965 only the two alternatives ,,more tired than usua'' and ,,more alert than usual'' were given, with the result that the experimental persons were,,compelle'' to choose one alternative or the other, or to leave the question unanswered. In the 1966 investigations a further alternative ,,unchange'' was allowed.

Comparison shows that the experimental persons treated with Cernilton in groups C and D show a higher percent of ,,more tired'' than those with placebo-treatment The frequency ,,more tired" is higher throughout for the placebo-treated persons in all four groups. A summing-up of all the experimental groups gives significance at the 10% level.

Finally, it should be said that only individuals with common cold symptoms in the four groups have been considered. The frequencies of ,,more alert'' and ,,more tired'' amongst the persons showing symptoms of colds are given. The tendency is thus amplified and the effects of Cernilton summed up over the groups then reaches the significance-level of 2.5%.

DISCUSSION

The field experiment carried out has not given an unquivocal result in relation to the prophylactic effect of the preparations used against the common cold. It has been shown that under certain conditions it is effective against some symptoms, that is, sore throat and coughing, in groups C and D. That the corresponding effects could not be deduced from groups A and F indicates the need for great caution in generalizing the results. It lies in the nature of the experiment that the Cernilton-treated and placebo-treated experimental persons are fully comparable within the units because of the,,blind'' randomizing. On the other hand, the four main groups themselves are not comparable on the same basis because of the different risks of being infected by the common cold, or of the type of infection experienced. Thus, fur example, group A consisted of a depot unit, which differs from the exercise units with relation both to the incidence of infection and the extent of strain experienced.

The frequency of visits to the doctor and sick-certification indicate that group D and F may have experienced heavier burdens than the two remaining groups. Here a clear distinction between Cernilton-treated and placebo-treated experimental persons has proved demonstrable both with relation to visits to the doctor and sick-certification.

The roborant effect of Cernilton has been evaluated on the basis of a question about condition. Here also groups C and D, and possibly F, give the clearest indication. It should be observed that the distinction is primarily expressed in a lower frequency of ,,tired'' amongst the Cernilton-treated persons. This occurs, naturally, in relation to the situation of the experimental persons, in which the burdens and the occurrence of common colds gives the least encouragement for individuals to report themselves as ,,more alert'' than usual. The results of the condition-question has also been considered separately for those individuals who declared themselves as suffering from some symptoms of the common cold. The object with this was to obtain a specially afflicted group for which any effect of Cernilton would have been particularly valuable. It is found that the effect in this analysis is most clearly expressed where the frequency of ,.more tired'' is lower throughout for all four units. The effect is most marked in group D, where none of the 26 sick persons in the Cernilton-treated group complain of having been ,,more tired''. The number of sick persons is admittedly relatively low, but the overall tendency gives nevertheless an unequiocally significant picture.

As we have already said, the results should not be generalized, at all events not to the extent that quantitative evaluations of the protective effect are given. It should also be remembered

in this connection that the experimental situation for military personel in training is an extremely specialized one.

It would be expected that in this situation, particularly when those concerned are aware that an experiment is being undertaken, that such persons would be extremely observant about their condition of health, and that tendencies to exaggeration may be found. This would not, however, be the reason for the observed effect of Cernilton, but it would make any quantitative evaluation very hazardous. All that should therefore be said for the present, therefore, is that the preparation under certain conditions combats the symptoms associated with infection of the upper air passage, and might for this reason be a useful prophylactic. The preparation has in addition shown during this investigation a roborant effect, in accordance with the observations already reported by Ask-Upmark [1], Glömme and Rasmussen [6] and Graudal [7].

Further elucidation of the conditions under which this effect arises, or the principle on which it is based, could not be provided by this field experiment, nor was this envisaged when it was undertaken.

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