

Double-Blind , Comparative, Clinical Study of the FH 84 and Placebo in Patients with Hay Fever

1989

1. Aim of the study

The aim of the single-centre, double-blind study was to compare the efficacy of a product containing standardized pollen extracts (FH 84) versus a placebo in patients with hay fever.

2. Patients and methods

The double-blind study was carried out in one hospital (Ospedale Maggiore Niguarda, Milan/Italy) under the supervision of Prof. Dr. C. Ortolani.

There have been two patient groups:

- The FH 84 group which received the pollen extracts (34 patients)
- The placebo group which received a non active component (41 patients)

The patients have been randomized to the two groups according a provided randomization list.

The structural homogeneity of the two groups in regard to the concomitant factors (age, sex, weather, wind) was assured.

The pollen extracts as well as the placebo have been given in powder form. The powders were filled in sachets and the patients had to take twice a day one sachet. A sachet with FH 84 contained 840 mg of a water soluble pollen extract (Cernitin T60), 42 mg of a fat soluble pollen extract (Cernitin GBX) and inactive ingredients ad 3000 mg.

A sachet with placebo contained 3000 mg inactive ingredients.

The patients received sachets for 30 days together with a form where they had to report daily their symptoms. The following symptoms were considered for the double-blind study:

- Ocular symptoms (itching, redness, and lacrimation)
- Nasal symptoms (sneezing, running nose and blocked nose)
- Pulmonary symptoms (asthma, dyspnoea and cough)

Every patient had to assess himself the symptoms by means of valuation scale:

0 = symptoms not present

1 = slight symptoms

2 = moderate symptoms

3 = severe symptoms

The statistical evaluation has been carried out by a simple data description and by the z-test for comparison of the mean values of two very large random samples. In the statistical tests the unilateral alternative hypothesis that the FH 84 treatment acts better than placebo was laid down.

3. Results

For the ocular symptoms, itching, redness and lacrimation, it can be demonstrated that under the treatment with FH 84 the mean intensity was lower than under placebo. The differences ranged from a trend to slight statistical significance ($0.04 < p < 0.10$). Here, considered globally, a slightly significantly better efficacy of the FH 84 treatment was thus to be observed.

For the nasal symptoms, sneezing, running nose and blocked nose, no better efficacy was observed under the treatment with FH 84 ($p > 0.45$).

For the pulmonary symptoms, asthma, dyspnoea and cough, a slight trend can perhaps be recognized for a somewhat better effect with FH 84 than with placebo ($0.05 < p < 0.15$).

During the whole study no patient of the two groups showed side effects. FH 84 as well as placebo have been very well tolerated.

FH 84 IN ALLERGIC RHINITIS

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However it seems, a statistical evaluation has not been done, that FH 84 had an additive effect when given together with other antiallergic agents.

In Italy a double-blind clinical study has been carried out in 1988. The first group (34 patients) received two sachets with FH 84 daily. The second group (41 patients) received two sachets with a placebo powder daily.

The efficacy of FH 84 and placebo on the following symptoms had to be observed:

- Ocular symptoms (itching, redness and lacrimation)
- Nasal symptoms (sneezing, running nose and blocked nose)
- Pulmonary symptoms (asthma, dyspnoea and cough)

There has been observed a slightly significantly better efficacy of FH 84 concerning the ocular symptoms whereas no better efficacy has been seen for the nasal symptoms. For the pulmonary symptoms a slight trend of a better efficacy with FH 84 than placebo has been found.

FH 84

FH 84 is a product containing standardized pollen extracts. FH 84 is used in the treatment of allergic rhinitis above all against hay fever.

FH 84 is presented in sachets of 3 grams and has the following composition:

- Cernitin T60
(water-soluble pollen extract)
840 mg
- Cernitin GBX

(fat-soluble pollen extract)

42 mg

- Inactive ingredients ad
3000 mg

Dosage: Twice a day 1 to 2 sachets in half a glass water

Side effects and contraindications: Have not been reported up to now.

Clinical studies with FH 84

In Switzerland (Tessin) in 1985 and 1986 44 patients with hay fever have been treated with FH 84. The patients have received 1-2 sachets with FH 84 daily.

A very good efficacy of FH 84 treatment has been observed in 6 patients (13.6%), a good efficacy in 15 patients (34%), a moderate efficacy in 10 patients (22.7%) and an insufficient efficacy in 13 patients (29.6%).

In Argentina a clinical study has been carried out in 1986 with three groups of patients.

The first group (17 patients) received one sachet with FH 84 a day. The second group (10 patients) received two sachets with FH 84 a day and to the third group (20 patients) was given daily one sachet with placebo.

Most of the patients of all three groups were treated besides the test substances (FH 84 or placebo) with other antiallergic agents. For this reason it must be said that the mostly good effects of the treatment have not been exclusively the result of FH 84 treatment.