BRIEF REPORT

TITLE: A double-blind, within patient comparative challenge study of budesonide nasal aerosol (Rhinocort®) and placebo

STUDY CODE: 005-2075

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STUDY OBJECTIVE

The aim of the study was to investigate if intranasally administered budesonide (Rhinocort®) exerts its effect on the nasal mucosa locally or systemically.

PATIENTS

The study was designed for 15 patients 15 - 55 years of age with a history of at least two seasons of typically recurring symptoms coincident with the pollen season. Patients should be asymptomatic when the challenge study was performed, the patients should also give a pronounced response of nasal obstruction as measured by interior rhinomanometry. The nasal challenge should be performed with a pollen allergen.

EXCLUSION CRITERIA

1. Diseases or conditions which might interfere with the evaluation of efficacy and safety, such as pregnancy or lactating women or women who may become pregnant during the study, infectious rhinitis, atrophic rhinitis, an allergy to corticosteroids, structural abnormalities such as severe septum deviations or nasal polyps, acute or chronic sinusitis or bronchitis, active tuberculosis, asthma, uncontrolled diabetes mellitus, infections not controlled by antibiotics, ocular herpes simplex or chicken pox, hypertension greater than 160/105, thrombophlebitis, active peptic ulcer, serious systemic diseases or acute psychoses.

2. Other therapy which might interfere with the evaluation of efficacy or adverse events: systemic corticosteroid therapy for any reason during the previous 3 months, allergen injections during the past 2 years, use of antihistamines, topical or oral decongestants, vasoconstrictors or other medications which could mask the symptoms of allergic rhinitis within one month of enrolment.

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3. Other reasons for exclusion: patients unable or unwilling to give an informed consent, patients known or felt to be uncooperative or unable to use medication according to direction, attend clinic or have laboratory tests.

METHODS

The trial was designed as a double-blind, randomised within patient study implying that the patients were to receive Rhinocort® in one nostril and placebo in the other simultaneously. The doses were to be 200 µg Rhinocort® bid or placebo. The medication was to be given to the patients for one week before the challenge with the last dose given two hours before challenge. At the first visit an optimal nasal response, which was not to produce total obstruction, was established in each patient. Nasal obstruction was measured by interior rhinomanometry

RESULTS

The trial was conducted during December 1983 and January 1984. Twelve patients entered the study and all patients completed and were considered in the statistical evaluations. Mean age of the patients was 30.2 years (range 20-39 years) and the mean duration of allergy was 12.3 years (range 3-30 years).

The nasal airway resistance results from the rhinomanometry measurements are displayed in Figure 1. As seen in the figure there was a significant increase of nasal resistance after provocation. This increase was statistically significant and greater in the placebo group than in the budesonide group, but the difference between treatments did not reach statistical significance. The significance was also tested for the area under curve but any difference in this parameter could not be detected either.

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In Figure 2 the symptoms (as assessed by the patients) 15 minutes after provocation are seen. Mean scores for budesonide were lower than placebo both for secretion and stuffy nose, but there was no significance between the treatments. Sneezing was also evaluated, but due to difficulties in determining differences between right and left nostril this variable was not used in the statistical analysis. To conclude the efficacy measurements there seems to be a slight improvement in the budesonide group, but there were no significances.

During the study no serious adverse experiences were reported and the only adverse event that occurred was defined as sneezing after spraying and occurred for one patient.
Figure 1: Nasal airway resistance

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Figure 2: Symptoms
15 min after provocation

- placebo
- budesonide