A Placebo Controlled Comparison of Two Dosage Regimens of Budesonide Nasal Powder (Rhinocort® Turbuhaler®)

Investigator(s): Dr W Fisher MB, ChB

Study Centre(s): The Clinic
Stirling Road
Fallin Road
STIRLING Scotland UK

Study Period: 17 May - 27 August 1991

Clinical Phase: IIb

Objectives: To compare the efficacy of two dosage regimens of budesonide nasal powder in the treatment of hayfever. Once and twice daily administration compared with placebo with respect to nasal symptoms registered in diary cards.

Study Design: Randomised, double-blind and parallel group design. Budesonide nasal powder 200μg bd or 400μg mane or placebo.

Number of Patients: 92 patients were randomised into the study: 32 to budesonide 200μg bd, 28 to budesonide 400μg mane and 32 to placebo. 72 patients completed and were valid for the all patients treated analysis, while 67 completed and were valid for the per protocol analysis.

Diagnosis and Criteria for Inclusion:
Male and female outpatients, aged 16 years or over having a diagnosis of hayfever for at least one year prior to study entry and presenting with at least two of the following symptoms: nasal blockage, sneezing, rhinorrhea or itchy nose and willing to give written consent. Patients were excluded if they had a history of nasal symptoms cutwith the hayfever period, visible nasal polyps, pronounced
deviation of nasal septum, use of systemic or nasal corticosteroids within four weeks of entry, respiratory tract infection at study entry or severe asthma.

**INVESTIGATIONAL PRODUCT:** Rhinocort Turbuhaler delivering either 100μg (batches DXC38 and DXC39) or 200μg (batch DXC36).

**REFERENCE THERAPY:** Placebo, Rhinocort Turbuhaler (batch DXC34).

**DURATION OF TREATMENT:** Three weeks.

**ASSESSMENT METHODS:** Diary cards, questionnaire and rhinoscopy. Mean scores for each symptom were calculated and group means computed. These were analysed using one way parametric analysis of variance followed by pair-wise comparisons using t-tests. Questionnaire data were evaluated using the Chi-square test. The primary analysis was an all patients treated analysis. Patients were only included in the analysis if they provided at least 3 days diary data.

**SUMMARY OF RESULTS:** Treatments with either dosage regimens of budesonide reduced mean nasal symptom scores compared with placebo. In all cases, these differences were statistically significant (p<0.05). Mean eye symptom scores and concomitant medication were similar for all 3 treatment groups. With respect to the questionnaire data, patients tended to rate the budesonide regimens as more effective than placebo, but the differences were not statistically significant. There were no serious adverse events in the study and no patients withdrew due to adverse events.

**CONCLUSION(S):** The efficacy of budesonide nasal powder (Rhinocort®) regarding nasal hayfever symptoms is similar when administered once or twice daily using a total daily dose of 400μg. Budesonide nasal powder dosed once or twice daily is more effective against nasal hayfever symptoms than placebo. Both dosage regimens of budesonide were well tolerated by the patients.

**DATE:** 13TH NOV 1996

**SIGNATURES:**

**AUTHOR**

**STATISTICIAN**