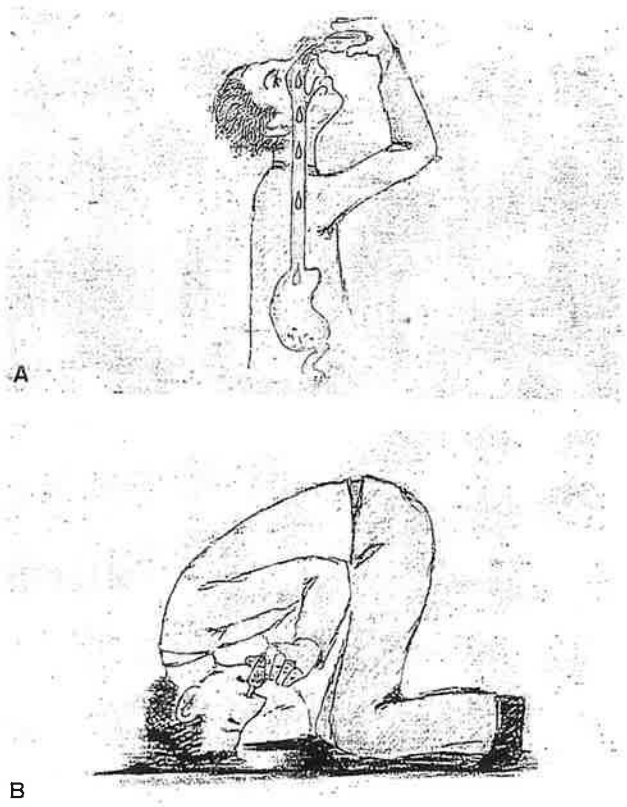

Figure 1. A) Administering drops in conventional position. B) Administering drops in head downwards and forwards position.

More recent studies in patients with nasal polyposis have shown that treatment with FP nasal spray can decrease the size of polyps and reduce the symptoms associated with polyposis (8–10). Objective measurements by an acoustic rhinometer have also shown an increase in nasal cavity volume after treatment with FP nasal spray (9).

Improved efficacy with FP nasal drops

The efficacy of nasal corticosteroids in nasal polyposis may be improved by changing the formulation in order to increase the dose delivered to the middle and upper meatus, where the polyps originate (11). The administration position is also important in the delivery of FP nasal drops for polyposis. If the drops are administered in the conventional way, with the head tilted back, the drops will only reach the lower region of the nose and the stomach, and not the upper region where the polyps originate (Fig. 1a). To achieve complete delivery to the target area, the patient must use the "head downwards and forwards" position (Fig. 1b). An alternative position is to lie face down on the bed, with the head hanging over the side (12). It is best to remain in these positions for a short time so the drops can reach the target site.

Recent clinical studies of FP nasal drops

Study design

Two multicentre, randomized, parallel studies have recently been conducted in patients with bilateral nasal polyposis to investigate the efficacy, dose-dependency and tolerability of FP 400 µg nasal drops administered once or twice daily (2, 3). All patients had mild (score 1) or moderate (score 2) polyps as assessed on the semiquantitative scale described by Johansen (13).

In both studies, the patients underwent the following trial periods: 2-week run-in, 12-week double-blind treatment, 12-week open treatment and 2-week follow-up (Fig. 2). In study 1, patients were randomized to receive either placebo (n=52) or FP 400 µg once daily (n=52). In study 2, patients were randomized to receive placebo (n=47), FP 400 µg once daily (n=48) or FP 400 µg twice daily (n=47). In both studies, all patients received FP 400 µg once daily during the second 12-week treatment period.

Measures of efficacy

The primary efficacy end point was polyp size. Polyp size was assessed by the investigators on a scale from 0 (none) to 3 (severe), depending on their position relative to the inferior turbinate (Fig. 3) (13). An improvement in polyp size required a change of at least one grade.

Secondary efficacy parameters included peak nasal inspiratory flow, symptom scores, olfactory function, use of rescue medication (loratadine) and the need for polypectomy. Peak nasal inspiratory flow was measured with a Youlten meter (14). Polyposis symptoms such as nasal blockage, sense of smell, nasal discomfort and rhinitis were assessed on a scale from 0 (absent) to 3 (severe) by both patients and physicians. Olfactory function was assessed by a modified version of the University of Pennsylvania smell identification test (15) and the butanol threshold test (16).

Results

In study 1, reductions in polyp size were observed in nearly 30% of FP recipients compared with 16% of placebo recipients; however, this difference did not reach statistical significance. A similar result was achieved in study 2 for