Methods

Subcutaneous specific immunotherapy (SCIT) with a high-dose hypoallergenic grass pollen preparation is known to be safe and effective. At present, increasing doses of an allergen preparation are administered in weekly intervals during the initial uptitration phase. To achieve the therapeutic target in less time and with fewer interventions, the safety of a shortened uptitration scheme was investigated.

Results

In a multicentre, open label, phase II trial with 2 parallel active treatment groups, 122 patients (Safety Set; Table 1) were 1:1 randomised either to the shortened uptitration arm receiving 4 injections (group I) or to the standard uptitration arm receiving 7 injections (group II; Figure 1). Both treatment groups received 2 additional maintenance doses. A total of 371 and 557 injections were administered in group I and II, respectively. Adverse events (AEs) were recorded during the whole treatment phase. Systemic reactions were graded according WAO criteria (1).

During the treatment phase AEs related to trial medication were observed in 22 (36.1%) patients of group I and in 15 (24.6%) patients of treatment group II. Local reactions were reported by 18 (29.5%) group I and 11 (18.0%) group II patients (Table 2). One (1.6%) patient (group II) revealed a serious adverse event (SAE) unrelated to trial medication. In group I, 5 WAO grade I systemic reactions were observed. In group II, 2 WAO grade I reactions occurred. WAO grade II reactions appeared 3 times in group I and 2 times in group II (Table 3). One systemic reaction in group I was not classified according WAO (PEF decrease without clinical symptoms).

The results show that the shortened uptitration with the high-dose hypoallergenic grass pollen preparation is safe and can be an optional treatment regimen for patients suffering from grass pollen allergic rhinoconjunctivitis with or without asthma.

Background

Subcutaneous specific immunotherapy (SCIT) with a high-dose hypoallergenic grass pollen preparation is known to be safe and effective. At present, increasing doses of an allergen preparation are administered in weekly intervals during the initial uptitration phase. To achieve the therapeutic target in less time and with fewer interventions, the safety of a shortened uptitration scheme was investigated.