titis with allergic rhino bronchitis and 10.7% of atopic dermatitis with upper respiratory diseases. Seventy five percentage patients were found to be primarily allergic to mites, 7.1% to pollens, 10.7% to cockroach and 7.1% to spores. Hundred percentage patients reported that they took the STRIPS regularly as directed by the physician. 64.3% of the patients reported their health improvement is good while 35.7% reported as very good. No adverse events were reported by any of the patients.

Conclusion: SLIT STRIP is found to be a more convenient dosage form to be stored at room temperature and in administering sublingual strip especially in pediatric patients over SLIT drops. Compliance and adherence to the intake of STRIPS is good and patient’s health improvement is also good.

### 340 Specific immunotherapy in atopic dermatitis

Calado, G; Ribeiro, C; Machado, D; Loureiro, G; Tavares, B; Pereira, C; Chieira, C
Coimbra University Hospitals, Immunology Department, Coimbra, Portugal

**Background:** Although the efficacy of specific immunotherapy (SIT) in allergic respiratory disease is well established, its application in atopic dermatitis has been a controversial issue. The aim of this study was to evaluate SIT efficiency in atopic dermatitis.

**Methods:** We included 29 patients with atopic dermatitis associated to house dust mites, allergic bronchial asthma and/or rhinitis. The severity of atopic dermatitis was evaluated using SCORAD in the beginning of the study (T0) and 1 year after the clinical treatment (T1). All the patients were controlled under medical treatment according to the severity of the disease. Group I included all patients submitted to SIT and group II included those without SIT (control group).

**Results:** The 29 patients included in this study (51.7% female, 48.3% male) had an average age of 19.31 ± 8.8 years of age. The patients included in group I and in group II had an average age of 20.58 ± 6.9 and 16.9 ± 11.7 years, respectively. SCORAD results (A - spread, B - intensity, C - subjective signs) are presented in the below table.

**Conclusion:** We observed that all SCORAD parameters improved after 1 year of SIT, with statistical significance (P < 0.05). Our data suggests that SIT is an effective treatment in patients with atopic dermatitis associated to allergic respiratory disease.

### 341 Safety and tolerability of recombinant Bet v 1 tablets in sublingual immunotherapy (SLIT)

Winther, L; Poulsen, L; Robin, B; Melac, M; Malling, H
National University Hospital, Allergy Unit 4222, Copenhagen, Denmark; StAllergenes SA, Medical Department, Antony, France

**Background:** Sublingual immunotherapy (SLIT) using standardized, recombinant allergen vaccines may enable a more reproducible clinical response.

**Methods:** Two single-centre, randomized, double-blind, placebo-controlled, parallel-group, Phase I clinical studies investigated the safety and tolerability of recombinant Bet v 1 (rBet v 1) sublingual tablets in subjects with birch pollen allergic rhinitis for at least 2 years. The first study investigated higher doses of rBet v 1 SLIT (50–300 μg), while the second investigated the 12.5–100 μg range. Ten doses of SLIT (fixed dose or maximum reach by titration) or placebo were administered. Safety and tolerability were assessed as well as physical examination, vital signs, clinical laboratory tests, 12-lead ECG and spirometry. Serum IgE and IgG4 levels were measured.

**Results:** There were a total of 402 treatment emergent adverse events (TEAEs) in 101 of the 112 (90%) enrolled subjects. Three hundred and twenty five TEAEs (81%) were SLIT-related, with the most common being oropharyngeal pruritus, ear pruritus, rhinitis and pharyngeal oedema. Fifty nine percentage of TEAEs were mild and 3% were severe. Ten SLIT subjects (12%) withdrew due to TEAEs (all occurring after administration of high doses between 50–300 μg). No serious AEs or deaths were reported. Immunological assays showed an increase in birch and/or Bet v 1 IgE titres in 69 out of 84 (82%) subjects and IgG4 titres in 30 out of 84 (36%).

**Conclusion:** rBet v 1 sublingual tablets were well tolerated up to a dose of 50 μg without the need for dose titration. Further studies are planned to identify the optimal effective dose.

### 342 Immunotherapy with recombinant Fel d 1 hypoallergen reduces allergic responses in a mouse model for cat allergy

Saanne, T; Neimert-Andersson, T; Gronlund, H; Bigdeli, N; Gafvelin, G; van Hage, M
Karolinska Institutet, Department of Medicine, Clin Immunology and Allergy Unit, Stockholm, Sweden

**Background:** We have previously constructed a hypoallergenic candidate of the major cat allergen Fel d 1 by duplicating selected T-cell epitopes and disrupting disulphide bonds. The hypoallergen, recombinant (r) Fel d 1 (DTE III), showed retained T cell reactivity and more than 1000 times reduced IgE-binding capacity compared to unmodified rFel d 1. The aim of this study was to evaluate rFel d 1 (DTE III) in our mouse model for cat allergy.

**Methods:** BALB/c mice were subcutaneously (s.c.) sensitized with rFel d 1 on day 0, 14 and 28. Groups of sensitized mice (n = 8–10) were therapeutically treated (s.c.) with 50 or 200 μg rFel d 1 (DTE III), 50 μg rFel d 1 or PBS on day 30, 32 and 34, prior to intranasal allergen challenge with cat dander extract (CDE) on day 39, 40 and 41. Airway hyperreactivity (AHR) and immunoglobulin levels in serum were analysed.

**Results:** Compared to PBS-treated/CDE-challenged mice, the mice treated with 200 μg rFel d 1 (DTE III) showed a reduced AHR to metacholine. Treatment with 50 μg rFel d 1 (DTE III) or 50 μg rFel d 1 did not result in a reduction in AHR. Only four out of ten mice survived treatment with 50 μg rFel d 1. Both treatment with 50 and 200 μg rFel d 1 (DTE III), and with 50 μg rFel d 1 resulted in a significant increase in the serum levels of rFel d 1-specific IgG1 and IgG2a, and a significant decrease of IgE compared to PBS-treated/CDE-challenged mice. The differences compared to PBS-treated/CDE-challenged mice were most prominent for the mice treated with 200 μg rFel d 1 (DTE III). This group of mice also had lower levels of serum-IgE to rFel d 1 compared to mice treated with 50 μg rFel d 1 (DTE III).

**Conclusion:** The rFel d 1 (DTE III) hypoallergen is a promising candidate for appli-