Subcutaneous immunotherapy with mannan-conjugated birch pollen allergoids is safe and well tolerated – data from 3 sequential trials

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S. Allekotte[1], E. Raskopf[1], L. England[1], C. Neuhof[1], H. Sahin[1], L. Radtke[1], C. Zeyen[2], L. Decker[2], E. Xenofontos[2], F. Hüffmeier[2], M. Cuevas[3], M. Casanovas[4], E. Fernandez-Caldas[4], J. L. Subiza[4], R. Mösges, FAAAAI[1,2]

[1]ClinCompetence Cologne GmbH, Cologne, Germany, [2]Med. Faculty, University of Cologne, Cologne, Germany, [3]University Hospital Carl-Gustav-Carus, Technical University Dresden, Dresden, Germany, [4]Inmunotek S.L., Alcalá de Henares, Madrid, Spain

Rationale

Subcutaneous immunotherapy has not only to be effective, but also needs to be safe and well tolerated in order to be accepted by physicians and patients. Here we show the safety data from 2 double-blind, placebo-controlled studies and 1 open follow-up study with mannan-conjugated birch pollen allergoids (T502).

Methods

The data of all patients who received pre-seasonal treatment with 10.000 mTU/mL T502 were analyzed. Safety and clinical tolerability were assessed by means of solicited and unsolicited adverse events (AEs) in all 3 studies and the data was then pooled.

Conclusions

Subcutaneous immunotherapy with T502 is safe and well tolerated with local and systemic reactions being comparable to other studies. A further dose split considerably improves the tolerability.

Results

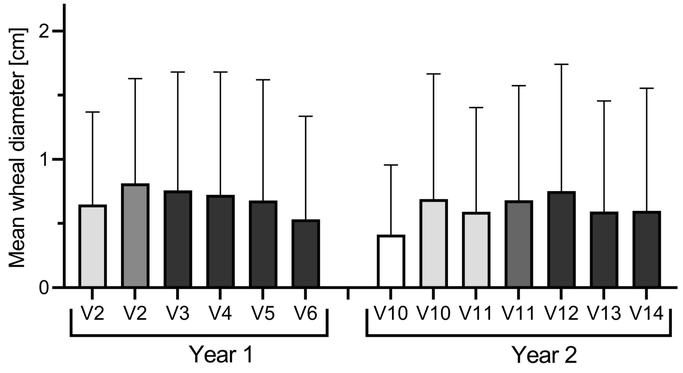

Figure 1: Exemplary development of imme-diate local reactions of the 2 years of the T502-SIT-041 study (mean wheal diameters) were all <6 cm (mean/ median: 0.63/0.4 cm) at all visits with 25% being 0 cm. Similar results were obtained for the studies T502-SIT-020 and T502-SIT-041. Data is expressed as mean wheal diameters +SD.

AWMF-Grading	Placebo		T502	
	N = 160 Pts	N = 1219 Inj.	N = 414 Pts	N = 3371 Inj.
Grade I	0.63%	0.08%	5.56%	0.45%
Grade II	0%	0%	2.97%	0.24%
Grade III	0%	0%	0%	0%
Grade IV	0%	0%	0%	0%
TOTAL	0.63%	0.08%	8.52%	0.69%

Table 1: In all 3 studies (T502-SIT-020, T502-SIT-041, T502-SIT-045), no fatality nor other serious adverse event in relation to T502 was reported. No epinephrine was used. No systemic reaction (SR) grade III or IV occurred.
In total, 23 systemic reactions according to the German AWMF grading were reported by 19 patients (4.5%, N=419). Broken down to the number of T502 injections (N=3371), SRs occurred in 0.7% of injections.

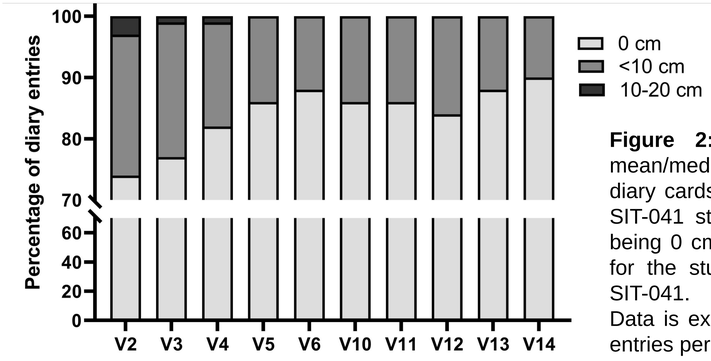

Figure 2: Exemplary development of mean/median wheals documented in the diary cards (late phase LRs) of the T502-SIT-041 study were 0.44/0 cm with 83% being 0 cm. Similar results were obtained for the studies T502-SIT-020 and T502-SIT-041.
Data is expressed as percentage of diary entries per visit.

MedDRA Preferred Term	Placebo		T502	
	N = 160 Pts	N = 1219 Inj.	N = 414 Pts	N = 3371 Inj.
Injection site pruritus	0.0%	0.00%	37.4%	4.60%
Pruritus	1.3%	0.16%	14.5%	1.78%
Injection site reaction	0.0%	0.00%	14.3%	1.75%
Injection site swelling	0.0%	0.00%	13.0%	1.60%
Peripheral swelling	0.0%	0.00%	12.3%	1.51%
Injection site pain	0.0%	0.00%	5.3%	0.65%
Local reaction	0.0%	0.00%	3.1%	0.39%

Table 2: Unsolicited AEs (pooled data from all 3 studies, T502-SIT-020, T502-SIT-041, T502-SIT-045) with a (possible) relationship to the IMP occurred in 46% of the patients.
Data is expressed as percentage of MedDRA Preferred Term (according to the investigators documentation) per all patients of the respective treatment group and per all injections of the respective treatment.

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