

Multi oral immunotherapy with omalizumab ‘real life’ study^{1,2}

A Phase 2 Study of Multi Oral Immunotherapy in Multi Food Allergic Patients to Test Immune Markers after Minimum Maintenance Dose

Sindher SB, et al. Allergy. 2022;00:1–12.



Aim

To investigate whether omalizumab improves the safety of multiple food allergen OIT (mOIT) in patients with multi food allergies and determine if treatment with omalizumab in conjunction with mOIT is associated with a lower required maintenance dose of each food allergen in the OIT regimen.

Participants

60 participants with **multi-food allergies**



2 centres



Median age **10 years**
(range 4–20 years)



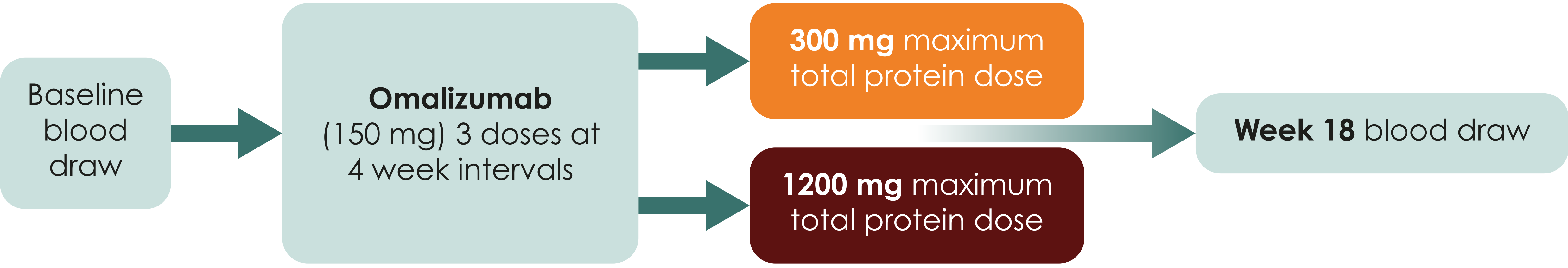
68% male



Allergic to **2–5 allergens**

Study design

Randomisation to two mOIT groups



Results

Primary end point		
slgG4/slge ratio increase of ≥25% from baseline for ≥2 allergens at week 18		
Maximum total protein dose 300 mg *	70% (21/30)	No difference between treatment groups (OR, 1.00; 95% CI, 0.29–3.49; P=1.00)
Maximum total protein dose 1200 mg *	70% (21/30)	

Secondary end point			
slgG4/slge ratio increase of ≥25% from baseline for at least 3, 4 and 5 allergens at week 18			
	3 allergens	4 allergens	5 allergens
Maximum total protein dose 300 mg *	56% (14/25)	20% (2/10)	50% (2/4)
	vs.	vs.	vs.
Maximum total protein dose 1200 mg *	48% (10/21)	46% (6/13)	0% (0/3)
	(OR, 1.39; 95% CI, 0.38–5.24; P=0.77)	(OR, 0.31; 95% CI, 0.02–2.51; P=0.38)	(OR, ∞; 95% CI, 0.14–∞; P=0.43)

Changes in ratio of food allergen slgG4/slge over time are associated with **clinical outcomes**. Though changes in slge may have resulted from omalizumab treatment, it was found that the observed increases in slge/slG4 ratio in this study was **driven primarily by an increase in IgG4**.

Safety

No differences in AEs were observed between the two groups
Rate of AEs was **19% in the 300 mg group** and **17% in the 1200 mg group** (P=0.69)
The most common AE was **gastrointestinal**



Conclusions

The data suggest plasma marker changes occurred early, even in patients treated with a total protein dose of 300 mg comprising multiple allergens, when mOIT was preceded with fixed-dose omalizumab. **Further research is needed to establish the optimal mOIT dosing when combined with omalizumab.**

CI, confidence interval; mOIT, multi-food oral immunotherapy; OIT, oral immunotherapy; OR, odds ratio; slgE, specific immunoglobulin E; slgG4, specific immunoglobulin G4.
* The overall protein volume was equal within each group, but the individual allergen maintenance dose varied depending on number of allergens included in the mix.
1. Sindher SB, Kumar D, Cao S, et al. Phase 2, randomized multi oral immunotherapy with omalizumab ‘real life’ study. Allergy. 2022;00:1–12.
2. NCT03181009. Multi OIT to Test Immune Markers After Minimum Maintenance Dose. Available at <https://clinicaltrials.gov/ct2/show/study/NCT03181009> (accessed 7 April 2022).