

THE LANCET

Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Anagnostou K, Islam S, King Y, et al. Assessing the efficacy of oral immunotherapy for the desensitisation of peanut allergy in children (STOP II): a phase 2 randomised controlled trial. *Lancet* 2014; published online Jan 30. [http://dx.doi.org/10.1016/S0140-6736\(13\)62301-6](http://dx.doi.org/10.1016/S0140-6736(13)62301-6).

Table A1: Baseline characteristics of study participants

		Control group (n=50)	Active group (n=49)
Age (years)	n	50	49
	Mean (SD)	11.9 (2.67)	12.4 (2.42)
	Median (range)	12.3 (7.2, 16)	12.3 (8.1, 16.3)
Sex	Male	72% (36/50)	69.4% (34/49)
Weight (kg)	n	47	49
	Mean (SD)	44.3 (16.4)	45.7 (15.5)
	Median (range)	39 (21, 82)	43 (23, 81)
Asthma	Yes	58% (29/50)	59.2% (29/49)
Eczema	Yes	54% (27/50)	49% (24/49)
Rhinitis	Yes	54% (27/50)	59.2% (29/49)
Family history of peanut allergy	Yes	70% (35/50)	63.3% (31/49)
Severity of worst clinical reaction WAO score ¹	Grade 1	51% (25/49)	40.8% (20/49)
	Grade 2	26.5% (13/49)	51% (25/49)
	Grade 3	18.4% (9/49)	6.1% (3/49)
	Grade 4	4.1% (2/49)	2% (1/49)
Other food allergy	Yes	26% (13/50)	20.4% (10/49)
FAQLQ-PF QoL score	n	20	19
	Mean (SD)	2.69 (1.60)	3.26 (1.26)
	Median (range)	2.28 (0.3, 5.54)	3.61 (0.47, 5.44)
Peanut SPT weal diameter (mm)	n	50	49
	Mean (SD)	8.54 (3.08)	8.92 (3.02)
	Median (range)	9 (3, 14)	9 (0, 16)
Other nut SPT weal diameter	<3mm	68% (34/50)	77.6% (38/49)
	≥3mm	32% (16/50)	22.4% (11/49)
Total IgE (kU/l)	n	50	49
	Mean (SD)	539 (467)	597 (844)
	Geometric mean	385.9	312.9
	Median (range)	355.5 (44, 1942)	295 (20, 3971)
Peanut specific IgE (kU/l)	n	50	49
	Mean (SD)	79.5 (117)	202.9 (539)
	Geometric mean	24.0	29.9
	Median (range)	41.6 (0.39, 463)	37.9 (0.35, 3649)

		Control group (n=50)	Active group (n=49)
Tryptase (ng/ml)	n	26	33
	Mean (SD)	4.55 (1.85)	5.10 (2.94)
	Median (range)	4.5 (1.7, 8.9)	4.9 (0, 15.6)
DBPCFC WAO severity score ¹	Grade 1	22% (11/50)	26.5% (13/49)
	Grade 2	74% (37/50)	67.3% (33/49)
	Grade 3	4% (2/50)	6.1% (3/49)
	Grade 4	0% (0/50)	0% (0/49)
DBPCFC: Total peanut protein consumed (mg)	n	50	49
	Mean (SD)	151.9 (274.0)	99.8 (76.8)
	Geometric mean	66.2	63.9
	Median	55 (5, 1400)	60 (5, 400)
DBPCFC: LOAEL (mg)	n	50	49
	Mean (SD)	147.9 (274.6)	94.6 (77.4)
	Geometric mean	63.5	58.1
	Median	55 (5, 1400)	55 (5, 400)
DBPCFC: NOAEL (mg)	n	50	49
	Mean (SD)	41.5 (80.1)	28.4 (36.8)
	Geometric mean	14.3	0
	Median	5 (5, 400)	5 (0, 155)
Basophil AUC of CD63MFI against peanut protein concentration	n	22	13
	Mean (SD)	34039 (27513)	40198 (33488)
	Geometric mean	205556	29271
	Median (range)	31438 (1219, 109006)	34955 (4930, 118532)
Basophil AUC of %CD63 positive cells against peanut concentration	n	22	13
	Mean (SD)	6505 (2774)	7322 (1609)
	Geometric mean	5205	7133
	Median	6958 (179, 9553)	7107 (3828 9284)

WAO=World Allergy Organization adapted score.¹ FAQLQ-PF=Food Allergy Quality of Life Questionnaire Parent Form. SPT=skin prick test. DBPCFC=double-blind placebo controlled food challenge. NOAEL=no observed adverse effect level (highest dose of peanut protein (mg) tolerated during baseline challenge). LOAEL=lowest observed adverse effect level (lowest dose of peanut protein (mg) which caused a reaction during baseline challenge). AUC=area under curve. MFI=mean fluorescent intensity.

Reference

1 Cox L, Larenas-Linnemann D, Lockey R, Passalacqua G. Speaking the same language: the World Allergy Organization Subcutaneous Immunotherapy Systemic Reaction Grading System. *J Allergy Clin Immunol* 2010; **125**: 569–74.

Table A2: Immunological endpoints

	Control n=46	Active n=39	p values
Within participant changes in SPT wheal diameter (mm)			
Median (range) change from baseline to post treatment	-1.5 (-8, 9)	-1 (-8, 4)	0.0693, 0.0015
Within participant changes in total IgE (kU/L) by group			
Median (range) change from baseline to post treatment	24 (-303, 1582)	99 (-164, 1411)	0.0109, <0.001
Within participant changes in serum peanut specific IgE (kU/L)			
Median (range) change from baseline to post treatment	74.5 (-55, 637)	12.7 (-18.6, 1359)	<0.001, <0.001

SPT=skin prick test, performed with single lancet technique using peanut extract, normal saline and histamine controls (ALK-Abello, Hørsholm, Denmark). Peanut specific IgE=peanut specific immunoglobulin E (kU/l) measured by ImmunoCap (ThermoFisher).