

## Assessing the efficacy of oral immunotherapy for the desensitisation of peanut allergy in children (STOP II): a phase 2 randomised controlled trial

Anagnostou K, Islam S, King Y, et al.

### BACKGROUND

Small studies suggest peanut oral immunotherapy (OIT) might be effective in the treatment of peanut allergy.

We aimed to establish the efficacy of OIT for the desensitisation of children with allergy to peanuts.

### METHODS

We did a randomised controlled crossover trial to compare the efficacy of active OIT (using characterised peanut flour; protein doses of 2-800 mg/day) with control (peanut avoidance, the present standard of care) at the NIHR/Wellcome Trust Cambridge Clinical Research Facility (Cambridge, UK). Randomisation (1:1) was by use of an audited online system; group allocation was not masked. Eligible participants were aged 7-16 years with an immediate hypersensitivity reaction after peanut ingestion, positive skin prick test to peanuts, and positive by double-blind placebo-controlled food challenge (DBPCFC). We excluded participants if they had a major chronic illness, if the care provider or a present household member had suspected or diagnosed allergy to peanuts, or if there was an unwillingness or inability to comply with study procedures. Our primary outcome was desensitisation, defined as negative peanut challenge (1400 mg protein in DBPCFC) at 6 months (first phase). Control participants underwent OIT during the second phase, with subsequent DBPCFC. Immunological parameters and disease-specific quality-of-life scores were measured. Analysis was by intention to treat. Fisher's exact test was used to compare the proportion of those with desensitisation to peanut after 6 months between the active and control group at the end of the first phase. This trial is registered with Current Controlled Trials, number ISRCTN62416244.

### FINDINGS

The primary outcome, desensitisation, was recorded for 62% (24 of 39 participants; 95% CI 45-78) in the active group and none of the control group after the first phase (0 of 46; 95% CI 0-9;  $p < 0.001$ ). 84% (95% CI 70-93) of the active group tolerated daily ingestion of 800 mg protein (equivalent to roughly five peanuts). Median increase in peanut threshold after OIT was 1345 mg (range 45-1400;  $p < 0.001$ ) or 25.5 times (range 1.82-280;  $p < 0.001$ ). After the second phase, 54% (95% CI 35-72) tolerated 1400 mg challenge (equivalent to roughly ten peanuts) and 91% (79-98) tolerated daily ingestion of 800 mg protein. Quality-of-life scores improved (decreased) after OIT (median change -1.61;  $p < 0.001$ ). Side-effects were mild in most participants. Gastrointestinal symptoms were, collectively, most common (31 participants with nausea, 31 with vomiting, and one with diarrhoea), then oral pruritus after 6.3% of doses (76 participants) and wheeze after 0.41% of doses (21 participants). Intramuscular adrenaline was used after 0.01% of doses (one participant).

### INTERPRETATION

OIT successfully induced desensitisation in most children within the study population with peanut allergy of any severity, with a clinically meaningful increase in peanut threshold. Quality of life improved after intervention and there was a good safety profile. Immunological changes corresponded with clinical desensitisation. Further studies in wider populations are recommended; peanut OIT should not be done in non-specialist settings, but it is effective and well tolerated in the studied age group.

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