

Real world safety and efficacy outcomes during oral immunotherapy with characterized peanut protein

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Objectives: To assess efficacy and adverse events observed in peanut allergic children undergoing peanut oral immunotherapy (PNOIT) in the UK's only peanut immunotherapy service.

Patients and Methods

- 220 children, aged 7-16y, attending the Cambridge Peanut Allergy Clinic for PNOIT
- Seven up-dosing steps of 2 to 200mg CA001 characterised peanut protein (Figure 1)
- Up-dosing occurred in allergy clinic with 2h observation; daily treatment continued at home
- The PNOIT initiation day had only a single low dose (2mg) and short stay (2h)

- 97% of patients successfully were able to continue to take the maintenance doses
- 68,000 doses of immunotherapy were consumed
- Day 1 single low-dose was well-tolerated with few symptoms and no drop outs (Figure 2)
- 93% tolerated a 1000mg peanut challenge (Figure 4b)
- Peanut SPT and serum IgE to peanut and Ara h 2 reduced significantly over 24m treatment (Figure 3)

- Adverse events (AEs), severity and treatment were recorded daily by families on diary cards and reviewed at up-dosing visits
- A 1000mg peanut protein stat dose challenge was offered after 12m treatment.
- Baseline investigations: peanut IgE median 52.8 kU/l; Ara h2 IgE 28.0 kU/l; peanut SPT 12mm

Results

- 84% of up-dosing and 97% maintenance doses were symptom free (overall 94%)
- Only 12% of AEs required oral antihistamines
- None had hypotension or collapse. 4.6% had respiratory symptoms including mild airway involvement.
- No patients required IM adrenaline during up-dosing visits or nebulised beta 2 agonists. Inhaled Salbutamol used in 0.003% cases
- Adrenaline was used in 8 (5%) patients; five patients (3%) withdrew from treatment.

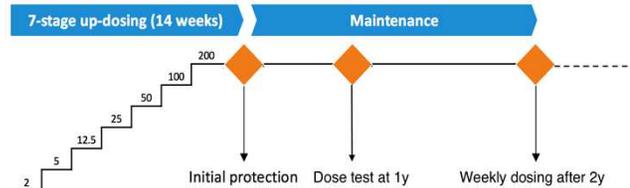


Figure 1. Updosing and maintenance treatment regimen; numbers represent milligrams of peanut protein consumed at each dose stage

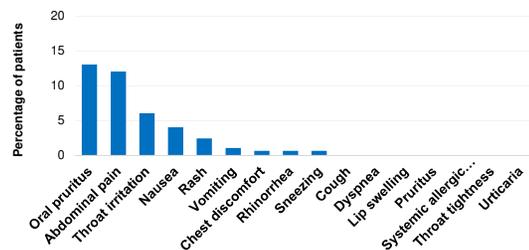


Figure 2: Adverse events on low-dose day 1 immunotherapy induction; percentage of patients who experienced each adverse event (all abdominal pain events were classified as mild)

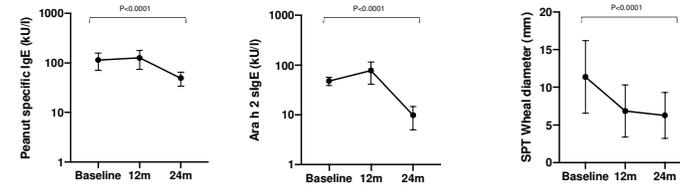


Figure 3. Change in mean (95%CI) peanut specific and Ara h 2 specific IgE (kU/l) and skin prick test wheal diameter (mm) during treatment

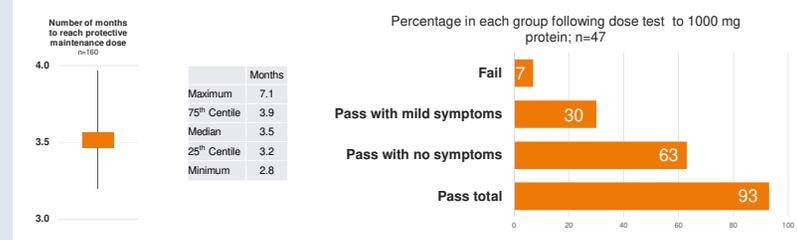


Figure 4a. Median time to maintenance treatment (months), Figure 4b. Percentage of patients who passed a 1000mg stat dose challenge after 12m PNOIT

- A short seven-stage regimen achieving maintenance dose in 3.5 months using characterised peanut protein was well tolerated, with few reactions and mostly minor symptoms
- A 1000mg challenge dose was well tolerated following OIT at 200mg maintenance dose

Conclusions

- The single, low-dose day-one PNOIT initiation was extremely well tolerated and safe
- Adrenaline was rarely used, and the withdrawal rate was far lower than that reported in published trials