



Translating science into tomorrow's treatments

A novel immunotherapy for peanut allergy

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Background:

Allergy to peanut is a common disease affecting 0.5 – 1.4% of children in high-income countries. It carries a great burden on the patient, their family and health services. Researchers from Addenbrooke's NHS Foundation Trust Cambridge have developed a novel immunotherapy, the first disease-modifying treatment for peanut allergy in the world.



Methodology:

The NIHR CRF Cambridge carried out a proof of concept study to find out if this new 'oral immunotherapy' is an effective treatment for peanut allergy.

Eligible participants were aged 7-16 years old with an immediate hypersensitivity reaction after peanut ingestion.

Participants were randomised to active therapy (peanut protein) or control and then gradually up-dosed at 2 week increments. Doses ranged from 2mg to an 800mg daily maintenance dose.

During the first phase the active group underwent 26 weeks of peanut oral immunotherapy and the control group 26 weeks of standard care (peanut avoidance).

At the end of the first phase participants were assessed for peanut allergy by double-blind, placebo-controlled food challenge.

During the second phase, participants in the control group still allergic to peanuts were offered peanut oral immunotherapy.

Results:

104 children were enrolled with a median age of 12.4 years. n=5 did not react during baseline peanut challenge, therefore n=99 were randomly assigned to study groups; n=49 active and n=50 control.

At the end of the first phase in the active group (24 of 39 participants; 62%, 95% CI 45-78%) compared with the control group (0 of 46; 0%, 95% CI 0-9.1; p>0.001. Absolute risk difference was estimated at 62% with a conservative 95% CI of 43-77.

After the second phase 91% (79-98) tolerated daily ingestion of 800mg peanut protein.



"I'm really glad I've taken part. It helps me because now I don't have to worry about eating peanuts.

It makes life so much easier ...other people should consider volunteering because it could save lives in the future."

JAMIE aged 14, study participant



Reference:

Anagnostou K et al (2014) Assessing the efficacy of oral immunotherapy for the desensitisation of peanut allergy in children (STOP II) a phase 2 randomised controlled trial, *Lancet* 12; 383 (9925): 1297-304

Contribution of the NIHR CRF:

The CRF provided expert clinical research nurses who carried out blood sampling and monitored safety of children taking part in this novel treatment which carried a high risk of anaphylaxis.



We have supported 1,400 flexible day case visits for 120 children taking part in the study. The CRF opened at weekends to minimise disruption to children's attendance at school and created additional day case space to accommodate additional visits.



The story of this developing treatment generated national and international coverage, in one day it was reported in 13 countries, in 973 articles and hit 15.8 million Twitter news feeds.

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