Study of induction of Tolerance to Oral Peanut: a randomised controlled trial of desensitisation using peanut oral immunotherapy in children (STOP II)

Katherine Anagnostou,1 Sabita Islam,1 Yvonne King,2 Loraine Foley,2 Laura Pasea,3 Chris Palmer,3 Simon Bond,4 Pamela Ewan1 and Andrew Clark1*

1Department of Medicine, University of Cambridge, Addenbrooke’s Hospital, Cambridge, UK
2Department of Allergy, Addenbrooke’s Hospital, Cambridge, UK
3Centre for Applied Medical Statistics, Department of Public Health and Primary Care, University of Cambridge, Institute of Public Health, Cambridge, UK
4Cambridge Clinical Trials Unit, Cambridge University Hospitals NHS Foundation Trust, Addenbrooke’s Hospital, Cambridge, UK

*Corresponding author

Declared competing interests of authors: Andrew Clark and Pamela Ewan are inventors on a patent application covering the peanut protein dose range.

Published December 2014
DOI: 10.3310/eme01040

Plain English summary

Study of induction of Tolerance to Oral Peanut (STOP II)
Efficacy and Mechanism Evaluation 2014; Vol. 1: No. 4
DOI: 10.3310/eme01040

NIHR Journals Library www.journalslibrary.nihr.ac.uk
Plain English summary

Peanut allergy is a common disease in developed countries, affecting up to 1% of children in the UK, France, Germany and the USA. Peanut allergy is most often diagnosed in children, but it can appear for the first time at any age. Reactions vary in severity, and include mouth itching, nausea, stomachache and vomiting. Itchy nettle sting-like rashes and swelling also occur. More serious reactions involve wheezing, throat tightness and shortness of breath, requiring hospital treatment. It is not possible to predict who is at most risk of a severe reaction.

Peanut allergy does not usually resolve and most children will grow into adults with peanut allergy. Currently, the best treatment is peanut avoidance, and patients manage this with varying success. Accidental reactions happen frequently, and families have to carry emergency medication all the time, including injectable adrenaline.

The quality of life (QoL) of families with children who have a peanut allergy is reduced because of constant fear of reactions and the social limitations they put in place to keep their children safe (e.g. not eating out).

Based on the encouraging results of a small pilot study, we undertook a randomised trial of a new treatment: peanut oral immunotherapy (OIT). This involved children eating increasing amounts of peanut under supervision, starting with a tiny amount and building up to the equivalent of five peanuts a day.

The results showed that a high proportion (80–90%) of peanut-allergic children could eat 4–6 peanuts regularly after treatment and that many (50–60%) can eat the equivalent of up to 10 peanuts at a time (primary outcome measure of the trial). At least in the short term (up to 2 years), children need to continue eating peanuts on a daily basis to maintain desensitisation. Common side effects of treatment included mouth itching and stomachache. Wheeze occurred after less than 1 in 200 doses and was treated with asthma inhalers. This treatment protects children from accidental ingestion and they can relax their avoidance practice. There was a significant improvement in QoL measure by a standardised questionnaire.

Peanut OIT is a promising novel treatment that appears to work well and with acceptable side effects. As this is the first study of its type, the findings are relevant to the population studied, but will require confirmation using other patient subgroups. Because of the complex treatment and monitoring involved, OIT should be restricted to specialist centres. This technique may be applicable to other foods and further studies are warranted.
Criteria for inclusion in the Efficacy and Mechanism Evaluation journal
Reports are published in Efficacy and Mechanism Evaluation (EME) if (1) they have resulted from work for the EME programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.
Efficacy and Mechanism Evaluation Editor-in-Chief

Professor Raj Thakker  May Professor of Medicine, Nuffield Department of Medicine, University of Oxford, UK

NIHR Journals Library Editor-in-Chief

Professor Tom Walley  Director, NIHR Evaluation, Trials and Studies and Director of the HTA Programme, UK

NIHR Journals Library Editors

Professor Ken Stein  Chair of HTA Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

Professor Andree Le May  Chair of NIHR Journals Library Editorial Group (EME, HS&DR, PGfAR, PHR journals)

Dr Martin Ashton-Key  Consultant in Public Health Medicine/Consultant Advisor, NETSCC, UK

Professor Matthias Beck  Chair in Public Sector Management and Subject Leader (Management Group), Queen's University Management School, Queen's University Belfast, UK

Professor Aileen Clarke  Professor of Public Health and Health Services Research, Warwick Medical School, University of Warwick, UK

Dr Tessa Crilly  Director, Crystal Blue Consulting Ltd, UK

Dr Peter Davidson  Director of NETSCC, HTA, UK

Ms Tara Lamont  Scientific Advisor, NETSCC, UK

Professor Elaine McColl  Director, Newcastle Clinical Trials Unit, Institute of Health and Society, Newcastle University, UK

Professor William McGuire  Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads  Professor of Health Sciences Research, Faculty of Education, University of Winchester, UK

Professor Jane Norman  Professor of Maternal and Fetal Health, University of Edinburgh, UK

Professor John Powell  Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK

Professor James Raftery  Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma  Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts  Professor of Child Health Research, UCL Institute of Child Health, UK

Professor Helen Snooks  Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Please visit the website for a list of members of the NIHR Journals Library Board:
www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact: nihredit@southampton.ac.uk