

Efficacy of the Enquiring About Tolerance (EAT) Study Among Infants at High Risk of Developing Food Allergy

Maes o ddiddordeb ymchwil: Food hypersensitivity

Hyd yr astudiaeth: 2016-10-13

Cod prosiect: FS101178

Cynhaliwyd gan: Kings College, London

Background

The purpose of Enquiring About Tolerance (EAT) Study was to examine whether early introduction of certain allergenic food into the diet of infants had an effect on the subsequent development of food allergy.

Further analyses of the EAT Study dataset adds to existing knowledge. These analyses explored the efficacy of the EAT studies' early introduction of allergenic food regimen amongst infants at high risk of developing food allergy. Risk factors associated with a higher risk of developing food allergy were defined as nonwhite infants; infants with visible eczema at enrollment; and/or infants with food sensitisation at enrollment.

It is hoped the results from this study will add to the evidence base that informs clinical advice and effective communication with families on the risks and benefits of allergenic food introduction for infants at high risk of developing food allergies.

Research Approach

The Enquiring About Tolerance (EAT) study recruited 1303 mothers and their infants onto the study from November 2009-July 2012. All mothers on the study were to breastfeed exclusively until their infants were 3 months of age at which point, they were randomly split into two groups.

One group (the Standard Introduction Group; SIG) followed standard UK government advice and were asked to exclusively breastfeed for around 6 months, after which introduction of allergenic foods was a matter of parental choice.

The second group (the Early Introduction Group; EIG) was asked to introduce 6 allergenic foods from the age of 3 months alongside continued breastfeeding with the help of a dietician and support from the study team.

It was important that breast milk remained an important part of all infants' diet during the first year of life, so all mothers in the study were encouraged to breast feed for at least six months regardless of study group.

All infants were closely monitored until 3 years of age when the impact of the intervention on food allergy and other additional allergy endpoints (such as eczema and asthma) were assessed and compared between the two study groups.

In the original EAT study the early introduction of allergenic food intervention, in the per-protocol analysis, did show a significant reduction in the prevalence of food allergy overall. However, in the intention-to-treat analysis, it did not achieve a statistically significant reduction in the rate of food allergy in the EIG vs the SIG.

Further analysis has now been performed to determine whether infants at high risk of developing a food allergy benefitted from early introduction.

Results

Efficacy of the EAT study amongst infants at high risk of developing food allergy

The Learning Early About Peanut (LEAP) study showed that infants at high risk of developing food allergy benefitted from the introduction of peanut. This analysis explored whether the EAT early introduction regimen was effective at reducing the rate of food allergy in those infants at high risk of developing such an allergy. Risk factors associated with a higher risk of developing food allergy were defined as non-white infants; infants with visible eczema at enrolment; and/or infants with food sensitisation at enrolment.

Key findings:

- In intention-to-treat analyses, infants with sensitisation to one or more foods at enrolment onto the study in the EIG developed less food allergy to one or more foods, and EIG infants with sensitization to egg developed less egg allergy.
- EIG infants with moderate severity eczema at enrolment developed less food allergy to one or more foods and less egg allergy

In the same way that the LEAP study reduced significantly the rate of peanut allergy in infants at high risk of developing food allergy, the EAT intervention reduced the rates of food allergy in infants at high risk of food allergy.

Published papers

Logan K, Perkin MR, Marrs T, Radulovic S, Craven J, Flohr C, Bahnson HT, Lack G. <u>Early Gluten Introduction and Celiac Disease in the EAT Study: A Prespecified Analysis of the EAT Randomized Clinical Trial.</u> JAMA Pediatric 2020.

Marrs T, Perkin MR, Logan K, Craven J, Radulovic S, Mclean IWH, Versteed SA, van Ree R, Lack G. Bathing frequency is associated with skin barrier dysfunction and atopic dermatitis at three months of age. Journal of Allergy and Clinical Immunology: In practise 2020. 8(8): 2820-2822.

Perkin MR, Logan K, Bahnson HT, Marrs T, Radulovic S, Craven J, Flohr C, Versteeg S, van Ree R, Lack G, EAT Study Team. Efficacy of the EAT study amongst infants at high risk of developing food allergy. Journal of Allergy and Clinical Immunology 2019. 114(6):1606-1614.

Perkin MR, Bahnson HT, Logan K, Marrs T, Radulovic S, Knibb R, Craven J, Flohr C, Versteeg S, van Ree R, Lack G, <u>EAT Study Team</u>. Factors influencing adherence in a trial of early introduction of allergenic food. Journal of Allergy and Clinical Immunology 2019. 144(6):1595-1605.

Voorheis P, Bell S, Cornelsen L, Gideon L, Perkin MR, <u>EAT Study Team. Challenges</u> experienced with early introduction and sustained consumption of allergenic foods in the <u>Enquiring About Tolerance (EAT) study: A qualitative analysis.</u> Journal of Allergy and Clinical Immunology 2019. 144(6):1615 -1623

Marrs T, Logan K, Craven J, Radulovic S, Irwin McLean WHA, Lack G, Flohr C, Perkin MR, <u>EAT Study Team</u>. Dog ownership at three months of age is associated with protection against food allergy. Allergy 2019. 74(11):2212-2219.

Fisher H, Du Toit G, Bahnson HT, Lack G. <u>The Challenges of Preventing Food Allergy: lessons</u> learned from LEAP and EAT. Annals of Allergy Asthma and Immunology 2018.121(3):313-319.

Perkin MR, Bahnson HT, Logan K, Marrs T, Radulovic S, Craven J, Flohr C, Lack G. <u>Association of early introduction of solids with infant sleep: a secondary analysis of a randomized clinical trial.</u> <u>JAMA paediatrics 2018</u>, 172(8), e180739.

Perkin MR, Logan K, Tseng A, Raji B, Ayis S, Peacock J, Brough H, Marrs T, Radulovic S, Craven J, Flohr C, Lack G; <u>EAT Study Team. Randomized Trial of Introduction of Allergenic</u> Foods in Breast-Fed Infants. N Engl J Med. 2016. 5;374(18):1733-43.

Perkin MR, Logan K, Marrs T, Radulovic S, Craven J, Flohr C, Lack G; <u>EAT Study Team.</u> Enquiring About Tolerance (EAT) study: Feasibility of an early allergenic food introduction regimen. Journal of Allergy and Clinical Immunology 2016. 137(5):1477-1486.e8.

Perkin MR, Craven J, Logan K et al. <u>The association between domestic water hardness, chlorine and atopic dermatitis risk in early life: A population based cross-sectional study. Journal of Allergy and Clinical Immunology 2016.</u> 138(2):509-516.

Flohr C, Perkin M, Logan K, et al. <u>Atopic dermatitis and disease severity are the main risk factors</u> for food sensitization in exclusively breastfed infants. J Invest Dermatol 2014. 134:345-50.

Flohr C, England K, Radulovic S, et al. <u>Filaggrin loss-of-function mutations are associated with early-onset eczema</u>, eczema severity and transepidermal water loss at 3 months of age. Br J Dermatol 2010. 163(6):1333-6.