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Two-step egg introduction for prevention of egg allergy in high-risk infants with eczema (PETIT): a randomised, double-blind, placebo-controlled trial

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Summary

Background

Evidence is accumulating that early consumption is more beneficial than is delayed introduction as a strategy for primary prevention of food allergy. However, allergic reactions caused by early introduction of such solid foods have been a problematic issue. We investigated whether or not early stepwise introduction of eggs to infants with eczema combined with optimal eczema treatment would prevent egg allergy at 1 year of age.

Methods

In this randomised, double-blind, placebo-controlled trial, we enrolled infants 4–5 months of age with eczema from two centres in Japan. Exclusion criteria were being born before 37 weeks of gestational age, experience of ingestion of hen's eggs or egg products, history of immediate allergic reaction to hen's eggs, history of non-immediate allergic reaction to a particular type of food, and complications of any severe disease. Infants were randomly assigned (block size of four; stratified by institution and sex) to early introduction of egg or placebo (1:1). Participants in the egg group consumed orally 50 mg of heated egg powder per day from 6 months to 9 months of age and 250 mg per day thereafter until 12 months of age. We aggressively treated participants' eczema at entry and maintained control without exacerbations throughout the intervention period. Participants and physicians were masked to assignment, and allocation was concealed. The primary outcome was the proportion of participants with hen's egg allergy confirmed by open oral food challenges at 12 months of age, assessed blindly by standardised methods, in all randomly allocated participants who received the intervention. This trial is registered with the University Hospital Medical Information Network Clinical Trials Registry, number UMIN000008673.

Findings

Between Sept 18, 2012, and Feb 13, 2015, we randomly allocated 147 participants (73 [50%] to the egg group and 74 [50%] to the placebo group). This trial was terminated on the basis of the results of the scheduled interim analysis of 100 participants, which showed a significant difference between the two groups (four [9%] of 47 participants had an egg allergy in the egg group vs 18 [38%] of 47 in the placebo group; risk ratio 0.222 [95% CI 0.081–0.607]; p=0.0012). In the primary analysis population, five (8%) of 60 participants had an egg allergy in the egg group compared with 23 (38%) of 61 in the placebo group (risk ratio 0.221 [0.090–0.543]; p=0.0001). The only difference in adverse events between groups was admissions to hospital (six [10%] of 60 in the egg group vs none in the placebo group; p=0.022). 19 acute events occurred in nine (15%) participants in the egg group versus 14 events in 11 (18%) participants in the placebo group after intake of the trial powder.

Interpretation

Introduction of heated egg in a stepwise manner along with aggressive eczema treatment is a safe and efficacious way to prevent hen's egg allergy in high-risk infants. In this study, we developed a practical approach to overcome the second wave of the allergic epidemic caused by food allergy.

Funding

Ministry of Health, Labour and Welfare, and National Centre for Child Health and Development, Japan.

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