The effect of hydrolyzed cow’s milk formula for allergy prevention in the first year of life: the German Infant Nutritional Intervention Study, a randomized double-blind trial.

BACKGROUND: The potential of extensively or partially hydrolyzed formulas to reduce the risks for allergies is controversial. OBJECTIVE: We sought to assess the preventive effect of differently hydrolyzed formulas compared with cow’s milk formula (CMF) in high-risk infants. METHODS: Between 1995 and 1998, 2252 infants with a hereditary risk for atopy were enrolled in the German Infant Nutritional Intervention Study and randomly assigned at birth to one of 4 blinded formulas: CMF, partially hydrolyzed whey formula, extensively hydrolyzed whey formula, and extensively hydrolyzed casein formula (eHF-C). The primary end point at 1 year of age was the presence of allergic manifestation, which was defined as atopic dermatitis (AD), gastrointestinal manifestation of food allergy, allergic urticaria, or a combination of these factors. RESULTS: At 12 months per protocol, analysis was performed on 945 infants exposed to study formula: 304 (13.5%) infants had left the study, 138 (6.1%) infants were excluded because of noncompliance, and 865 infants were exclusively breast-fed the first 4 months of life. The incidence of allergic manifestation was significantly reduced by using eHF-C compared with CMF (9% vs 16%; adjusted OR, 0.51; 95% CI, 0.28-0.92), and the...
incidence of AD was significantly reduced by using eHF-C (OR, 0.42; 95% CI, 0.22-0.79) and partially hydrolyzed whey formula (OR, 0.56; 95% CI, 0.32-0.99). Family history of AD was a significant risk factor and modified the preventive effect of the hydrolysates. CONCLUSIONS: Prevention of allergic diseases in the first year of life is feasible by means of dietary intervention but influenced by family history of AD. The preventive effect of each hydrolyzed formula needs to be clinically evaluated.