

Giampietro *et al.*, Hypoallergenicity of an extensively hydrolyzed whey formula. *Pediatr Allergy Immunol.* 2001; 12(2):83-6.

Abstract

Several different protein hydrolysate-based infant formulas have been promoted as hypoallergenic and considered suitable for the dietary management of cow's milk allergy (CMA). Accepting that none of the hydrolysate-based products is completely safe, the American Academy of Pediatrics (AAP) recommends that these formulas should be tested in a double-blind placebo-controlled setting and tolerated by at least 90% of children with proven CMA. In principle, this recommendation is also endorsed by the European Society of Paediatric Gastroenterology and Nutrition (ESPGAN) and the European Society of Paediatric Allergy and Clinical Immunology (ESPACI). In this two-center study, 32 children with proven CMA were tested with the extensive hydrolysate whey formula Nutrilon Pepti, for comparison with Profylac (extensive) and Nan HA (partial) whey hydrolysate products. Skin-prick tests (SPTs) were, respectively, positive to the three hydrolysate formulas in 19%, 15%, and 32% of children. After oral challenge it was concluded that 97% (95% CI: 85-100%) of the children tolerated Nutrilon Pepti, 94% (95% CI: 75-100%) tolerated Profylac, and 64% (95% CI: 37-81%) tolerated Nan HA. This study demonstrates that the extensive hydrolysates Nutrilon Pepti and Profylac are well tolerated in a population of children with proven CMA and that both products can be considered safe for their intended use. This study confirms that a very small number of children react even to extensively hydrolyzed formulas. SPT prior to oral exposure to the hydrolysate-based formulas can indicate whether a child is at risk of showing reactions to the product. Introduction of new products to these children should be carried out under a doctor's supervision. However, the majority of the SPT-positive children did tolerate the two extensively hydrolyzed whey-based formulas tested.