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HEALTHCARE PROFESSIONAL USE ONLY

NUTRICIA
Pepticate™



THE SCIENCE BEHIND PEPTICATE™
FOR THE MANAGEMENT OF
COW MILK ALLERGY (CMA)
FROM BIRTH

PEPTICATE
EVIDENCE BOOKLET

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Supporting evidence for Pepticate for management of CMA from birth

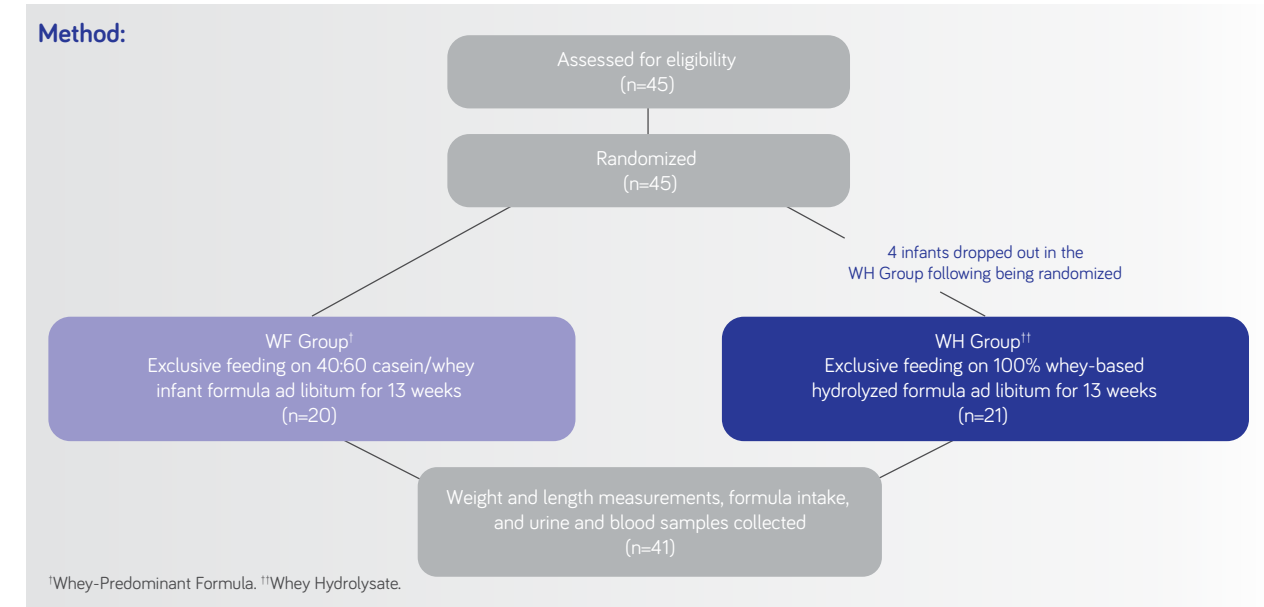
1. **The nutritional value of a whey hydrolysate formula compared with a whey-predominant formula in healthy infants.**
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The nutritional value of a whey hydrolysate formula compared with a whey-predominant formula in healthy infants.

Vandenplas Y et al. JPGN 1993;17(1): p.92-6.

Background: Over the last decade, formulas containing hydrolyzed protein in addition to specific ingredients such as pre and probiotics, have become of increasing interest in infant feeding, particularly for the management of allergy and allergic symptoms.

Aim: The aim of this study was to evaluate the nutritional value of whey hydrolysate formulas in healthy infants with no atopic disease or family history of allergy.



Results: Weight and length at week 13 were similar in both groups, despite a significantly lower intake (mean volume per day) in the hydrolysate group. Both WF and WH groups laboratory results were within normal limits.

Figure 1: Birth weight and weight gain in all infants at week 13

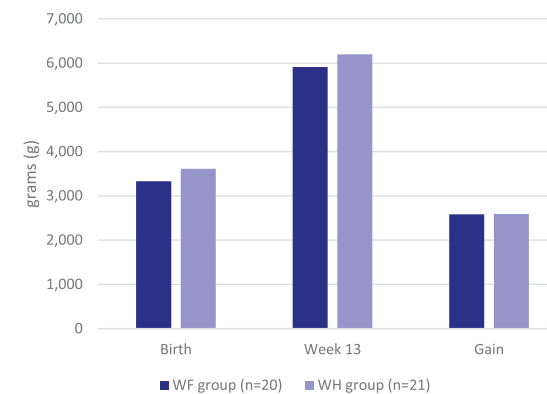
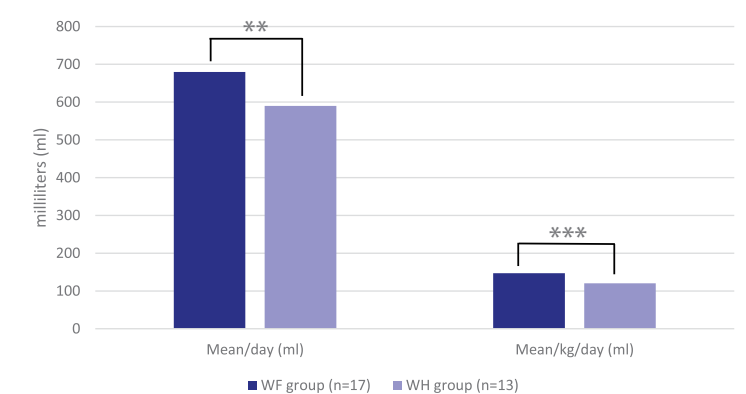


Figure 2: Mean volume intake in both groups*



*insufficient data collected for total group **p<0.002 ***p<0.001

The use of Pepticate results in an adequate nutritional status in healthy infants.

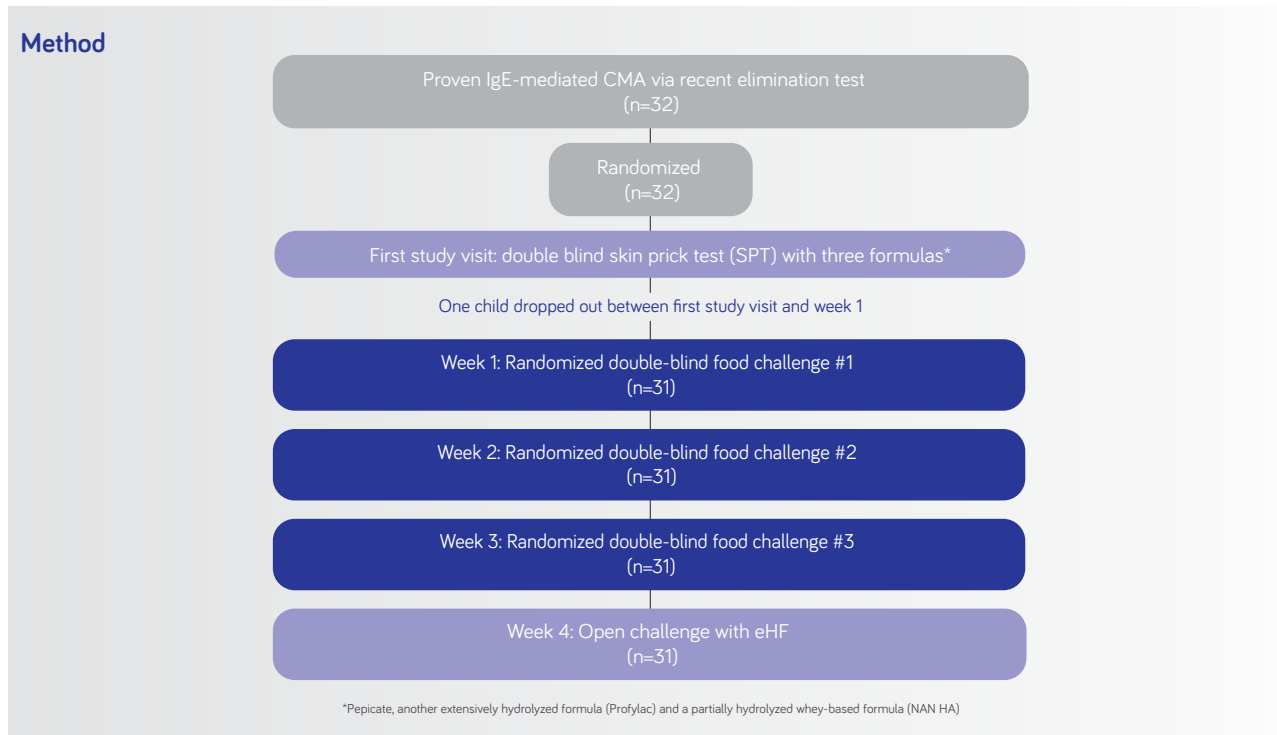
This study was conducted using Pepticate which is sold under various brand names worldwide.

Hypoallergenicity of an extensively hydrolyzed whey formula.

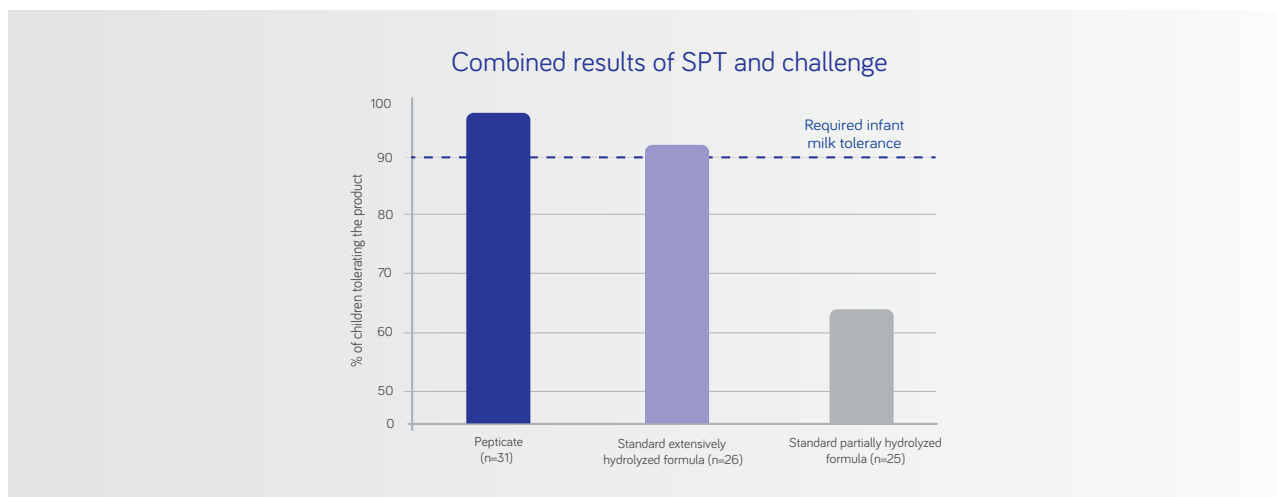
Giampietro PG et al. *Pediatr Allergy Immunol* 2001;12: p.83-6.

Background: The criteria for selection of a hypoallergenic formula has been set by governing bodies (such as the American Academy of Pediatrics (AAP)) to be effective and safe if it is proven to be tolerated by at least 90% of CMA infants.

Aim: The aim of this study was to investigate the hypoallergenicity of Pepticate according to the AAP guidelines.



Results: This study demonstrates that both extensive hydrolysates are well tolerated in a population of children with proven CMA and that Pepticate can be considered safe for its intended use.



Pepticate is clinically shown to be safe and well tolerated in 97% of infants with diagnosed CMA, therefore meeting AAP Guidelines criterion.

Symptomology and growth in infants with cow's milk protein allergy using two different whey protein hydrolysate-based formulas in a Primary Health Care Setting.

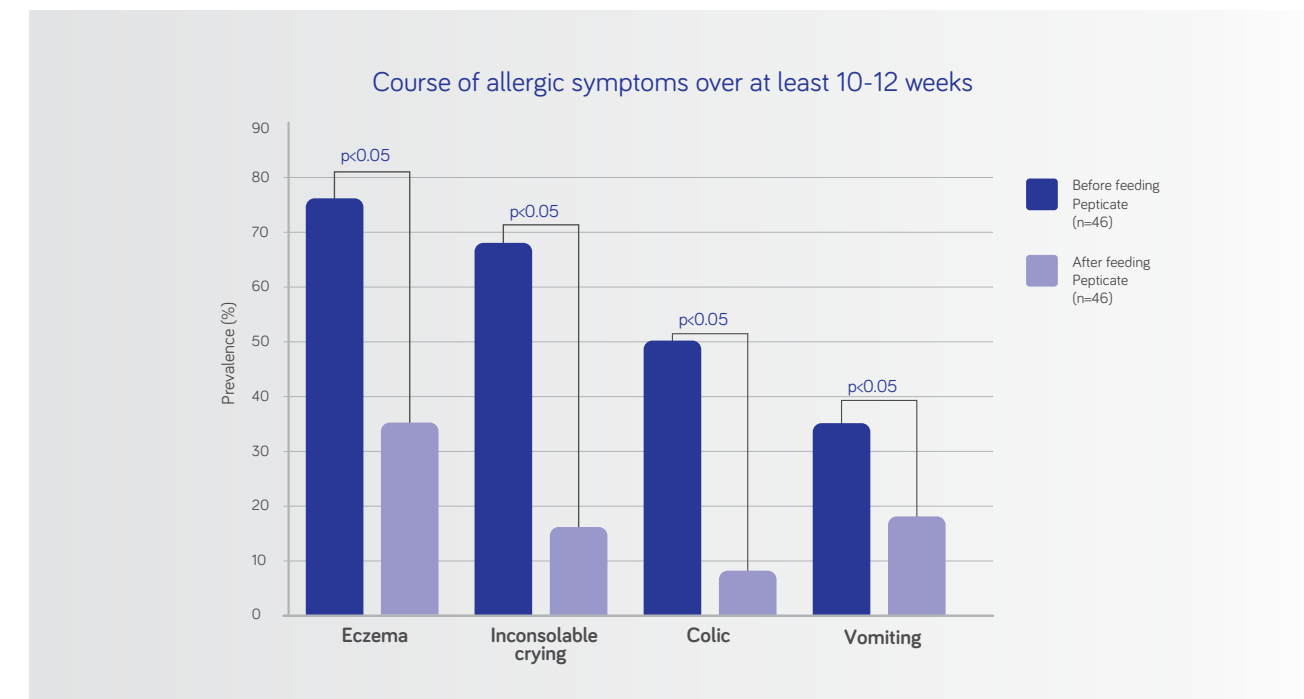
Verwimp JJM et al. *Eur J of Clin Nutr* 1995;49(Suppl 1); S39-S48.

Background: Treatment approaches towards cow milk allergy (CMA) differ widely across countries. Therefore it was felt that clinicians needed to start working towards a standard protocol, including a practical approach towards diagnosis and treatment of CMA patients.

Aim: The aim of this multi-center study was to investigate both the growth and course of allergic symptoms in 79 infants with CMA aged ≤ 3 months, diagnosed by standard elimination/challenge and treated with a whey hydrolysate-based infant formula.

Method: Growth and symptomology (skin, respiratory tract, gastrointestinal tract) were monitored throughout an intervention period of at least 10 weeks in a clinical setting and results were compared to a larger study. Subjects were randomized to receive an elimination diet of one of two hydrolyzed formulas to be used as a sole source of nutrition for the first 2-3 weeks. The hydrolyzed formulas consisted of an extensively hydrolyzed whey-based formula containing 50% MCT and no lactose (Pepti Junior) and an extensively hydrolyzed whey protein-based formula containing lactose and a more standard fat blend (Pepticate). When symptoms decreased during the elimination period, a standardized cow's milk challenge was performed with diagnosis of CMA confirmed one week after challenge. Thus diagnosed CMA infants continued the use of formula for three to four months, during which time they would visit a baby center once per month for standardized data collection on weight and symptomology. In addition, parents were asked to complete a specially designed form on a weekly basis to record the presence or absence of symptoms as well as events that might have influenced symptomology (such as infections, incoming teeth, use of drugs). These forms were used to score symptoms within the clinic.

Results: Infants in both feeding groups showed normal growth during the intervention period and at least 80% of the infants showed an improvement in overall symptomology. **Most profound were the decreases in prevalence and severity of eczema and infantile colic.** No differences in efficacy were found between the two infant formulas.



Pepticate is clinically shown to relieve symptoms (decrease in prevalence and severity of eczema and infantile colic)* and support normal growth in infants with CMA.

*Based on parent reported data.

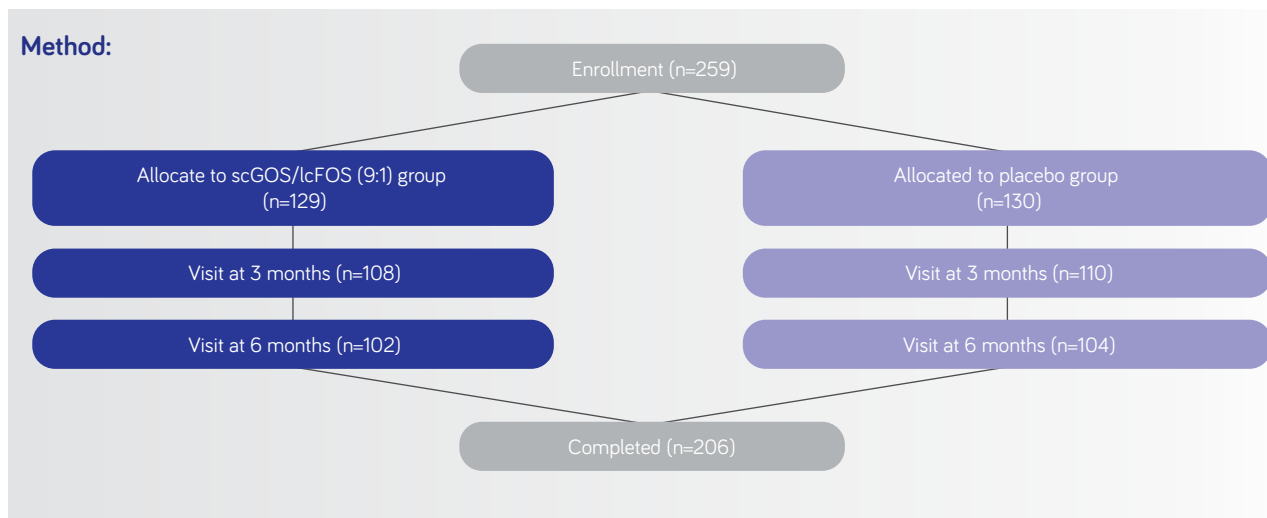
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A mixture of prebiotic oligosaccharides reduces the incidence of atopic dermatitis during the first six months of age.

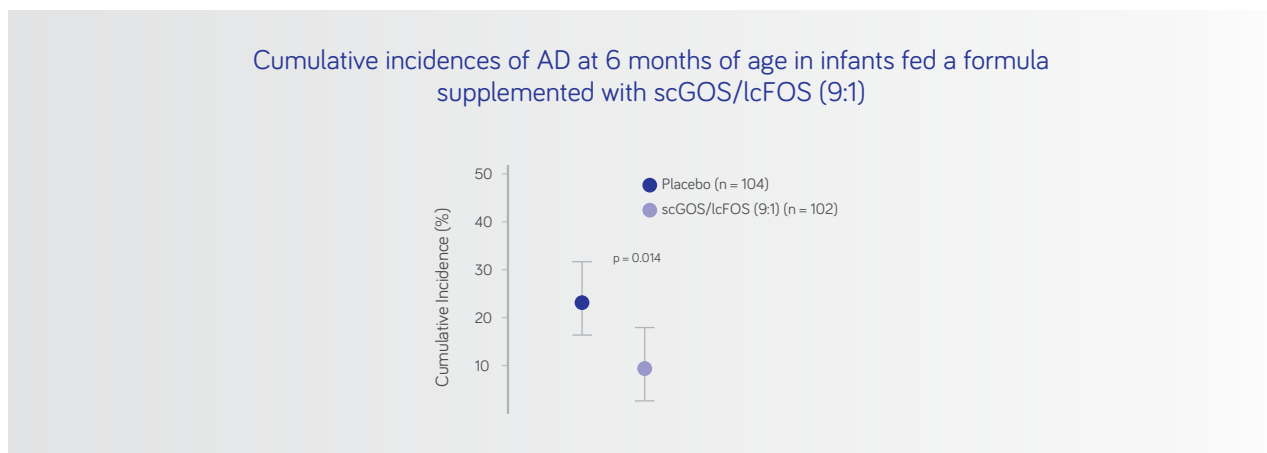
Moro G et al. Arch Dis Child 2006;91: p.814-9.

Background: The prevalence of atopic diseases has steadily increased during the last decade in developed countries. The composition of the intestinal flora plays a key role in postnatal development of the immune system. In human milk, oligosaccharides are an important factor that promote an intestinal flora dominated by bifidobacteria and lactobacilli. Based on the analysis of human milk oligosaccharides (HMO), a prebiotic blend of 90% short chain galacto-oligosaccharides (scGOS) and 10% long chain fructo-oligosaccharides (lcFOS) has been developed. Studies in infants have shown that feed supplementation with scGOS/lcFOS (9:1) produces an intestinal flora similar to that found in breast fed infants.

Aim: To investigate the effect of a specific prebiotic blend of galacto- and long chain fructo-oligosaccharides, used in combination with extensively hydrolyzed whey protein (Pepticate), on the incidence of atopic dermatitis (AD) during the first six months of life in formula fed infants at high risk of atopy.



Results: Ten infants (9.8%; 95 CI 5.4–17.1%) in the intervention group and 24 infants (23.1%; 95 CI 16.0–32.1%) in the control group developed AD. The severity of the dermatitis was not affected by diet. Prebiotic supplements were associated with a significantly higher number of fecal bifidobacteria compared with controls but there was no significant difference in lactobacilli counts.



Pepticate is demonstrated to beneficially modulate the gut microbiota and reduce incidence of atopic dermatitis in infants at high risk of atopy.

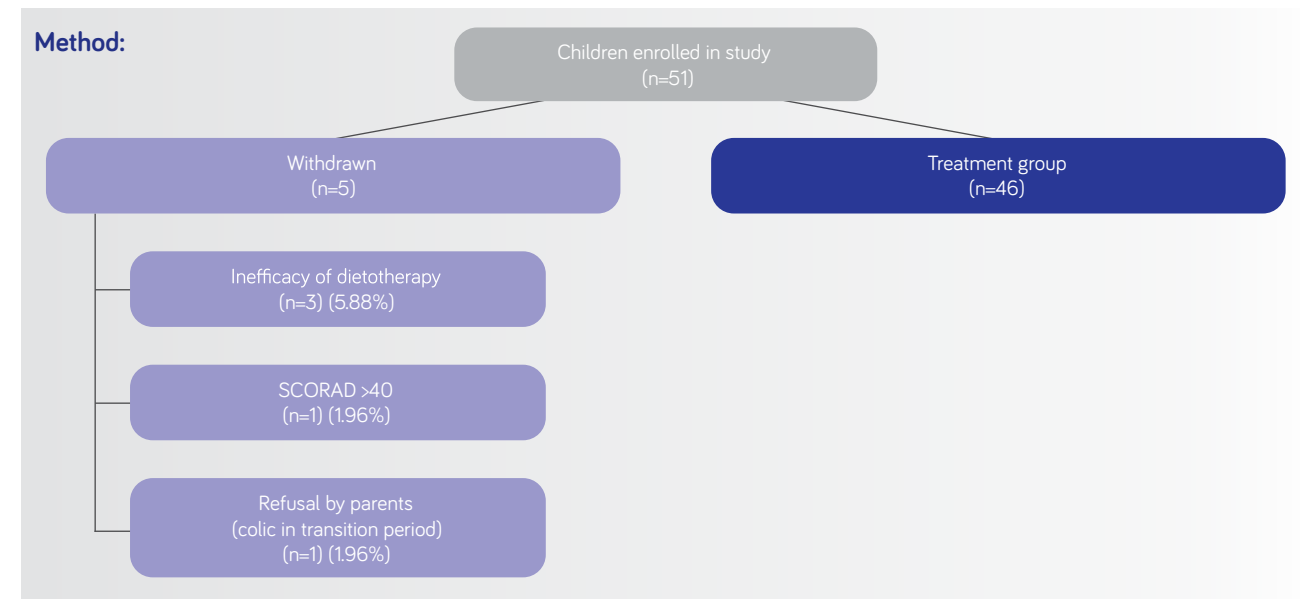
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A highly hydrolyzed formula based on whey protein with prebiotic galacto-oligosaccharides and fructo-oligosaccharides effectively abolishes the symptoms of atopic dermatitis: Results of a multi-center open-label trial in Russia.

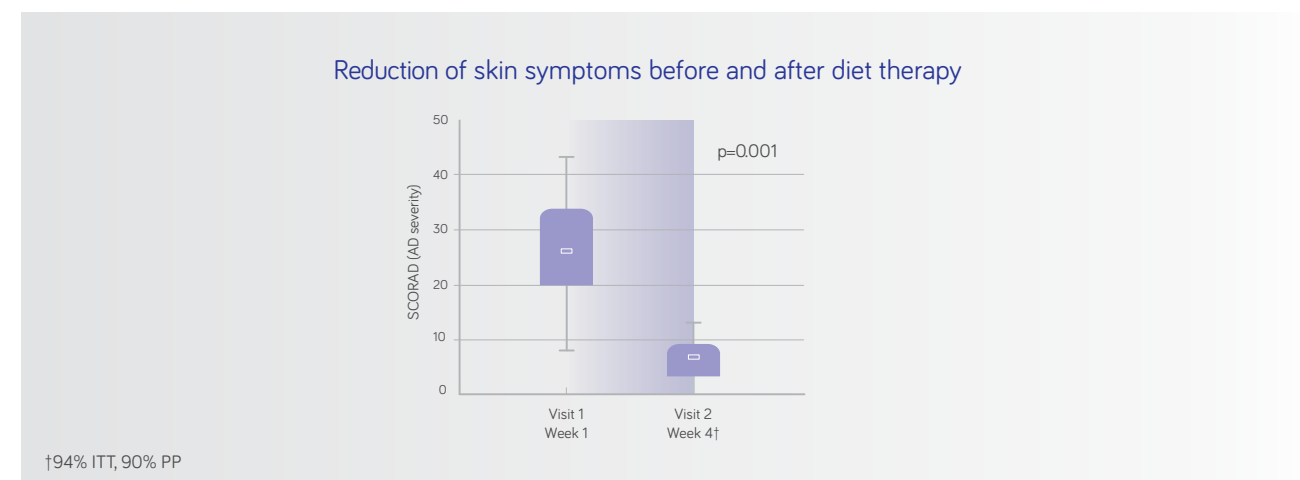
Pampura AN et al. Ros Vestn Perinatol Paediat 2014;4: p.96–104.

Background: Atopic dermatitis (AD) is common in children up to one year of age, who in the majority of cases suffer from a cow milk allergy (CMA). The main timely and successful medical treatment of such children is diet therapy with extensively hydrolyzed formulas.

Aim: The aim of this study was to evaluate the efficacy of an extensively hydrolyzed whey-based formula with a specific prebiotic blend of short chain galacto-oligosaccharides and long chain fructo-oligosaccharides (scGOS/lcFOS (9:1)) at a level of 0.8mg/100ml for infants of up to one year of age who were administered bottle-fed nutrition and suffered from AD, presumably associated with CMA.



Results: There was significant and notable resolution of AD symptoms - SCORAD score from 26.66 to 6.63. Also, during intervention, the need for topical therapy was notably lowered: glucocorticosteroids (more than 80%), zinc-containing medication (by 92%), systemic antihistamines or steroids (100% reduction).



Early use of Pepticate with a specific prebiotic blend scGOS/lcFOS (9:1) reduces allergic symptoms and improves stool consistency, in infants with AD and with suspected CMA, within 2–4 weeks.

This study was conducted using Pepticate which is sold under various brand names worldwide.

Palatability of Hypoallergenic Formulas for Cow's Milk Allergy and Healthcare.

Maslin K et al. *Pediatr Allergy Immunol.* 2018 Dec;29(8):857-862.

Background: Cow milk allergy (CMA) is the most common food allergy in infants in the United Kingdom. Infants with CMA who are not exclusively breastfed require a substitute hypoallergenic formula, which are perceived as having a poor palatability. This study compares the palatability of different extensively hydrolyzed formulas (eHFs) and explores healthcare professional (HCP) expectations of how palatability impacts infants and their families.

Methods: HCPs with experience of CMA were recruited to take part in a home palatability test of four eHFs available in the UK [Pepticate, Nutricia Ltd. (eHFs W1), Althéra, Nestle Health Science (eHFs W2), Similac Alimentum, Abbott (eHFs C1), Nutramigen LGG 1, Mead Johnson (eHFs C2)] using a blind taste procedure. A randomized, complete block design was used to minimize order and carry-over biases. Participants completed a questionnaire about the impact of formula palatability on infants and their families.

Results: 100 HCPs took part (51 dietitians and 49 general practitioners). Overall whey-based lactose-containing eHFs were ranked the most palatable: eHFs W1 by 77% of participants, eHFs W2 by 20%. eHFs W1 was liked significantly more ($p < 0.0001$) than the other formulas. The vast majority of participants agreed that better palatability would result in an increased chance of non-rejection (96%), more content families (92%) and decreased healthcare costs (90%).

Conclusion: Amongst HCPs who manage infants with CMA, whey-based lactose-containing eHFs were ranked the most palatable. HCPs expected that good palatability would result in better acceptance, more content infants and families, alongside decreased wastage and health care costs.

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Glossary of terms

AAP	American Academy of Pediatrics	HCP	healthcare professional
AD	atopic dermatitis	HMO	human milk oligosaccharides
CI	confidence interval	lcFOS	long chain fructo-oligosaccharides
CMA	cow milk allergy	scGOS	short chain galacto-oligosaccharides
eHF	extensively hydrolyzed formula	SCORAD	Scoring Atopic Dermatitis
HCP	healthcare professional	SPT	skin prick test

IMPORTANT NOTICE: Pepticate is a hypoallergenic, extensively hydrolyzed infant formula for use under medical supervision and is indicated for cow milk allergy.

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