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Effect of the specific infant formula mixture of oligosaccharides on local immunity and development of allergic and infectious disease in young children: randomized study



Wpływ żywienia mieszanką mleczną zawierającą oligosacharydy na miejscową odporność i rozwój chorób alergicznych i infekcyjnych u niemowląt: badanie randomizowane

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ABSTRACT

Aim: The aim of our open prospective randomized nutritional intervention study was to evaluate the effect of feeding with a standard infant formula enriched with the specific mixture of oligosaccharides on local digestive immunity system and further development of allergic and infectious diseases in young children. **Material and methods:** Depending on the type of feeding the infants were divided into 3 groups (with random allocation to one of the formula feeding groups): 80 infants who were breastfed, 80 infants consuming the formula supplemented with oligosaccharides, 80 infants fed with a standard formula. **Results:** Breastfed infants had the highest content of Bifidobacteria and Lactobacilli in feces (9.047 ± 1.075 and 7.26 ± 0.65 CFU/g accordingly). In infants fed with formula supplemented with scGOS/lcFOS fecal concentrations of Bifidobacteria and Lactobacilli were similar to those in breastfed infants (8.92 ± 1.011 and 7.22 ± 0.74 CFU/g accordingly). It was found that infants fed with breast milk and supplemented formula had significantly less allergic reactions to food products compared to the babies from the third group (3.92% and 4.84% vs. 16.98% accordingly; $p < 0,05$). **Conclusions:** The mixture of prebiotic oligosaccharides (scGOS/lcFOS – 9:1; 8 g/L) has a similar to breast milk positive impact on the factors of local digestive immunity system in formula-fed infants. This effect may reduce the risk of allergic and infectious diseases in children aged up to 18 months of life, compared with babies fed with the standard formula without oligosaccharides.

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Introduction

The influence of breast milk on the development of immunity was known many years ago. Human milk oligosaccharides have influence on the development of immunity and morbidity in infants. The type of diet is one factor that determines the composition of the intestinal microflora of breast-fed infants, which differs from the microflora of bottle-fed infants [1, 2]. In breastfed infants, the intestinal microflora is dominated by Bifidobacteria and Lactobacilli, and this microbial pattern produces beneficial effects on intestinal function and on development of the immune system [2, 3].

Based on the analysis of human milk oligosaccharides (HMO), a prebiotic mixture of 90% short chain galactooligosaccharides and 10% long chain fructo-oligosaccharides (scGOS/lcFOS (9:1; 8 g/L)) has been developed [4, 5].

Studies in preterm [6] and term [2, 7-8] infants have shown that feed supplementation with GOS/FOS produces an intestinal flora similar to that found in breast fed infants. Study showed that the use of this prebiotic oligosaccharide mixture (scGOS/lcFOS) can significant reduction of the total number of infections, respiratory tract infections, fever episodes, and antibiotic prescriptions during the first 2 y of life. The atopic dermatitis (AD), cumulative incidence of other allergy-associated symptoms, like recurrent wheezing and allergic urticaria, was also significantly lower in the scGOS/lcFOS group compared with the placebo group [9].

Our hypothesis was that this mixture of prebiotic oligosaccharides could mimic the immune modulatory function of HMO on local immunity factors, protect mucous membranes of the digestive system, and lead to a reduction in the incidence of allergic and infectious diseases in formula-fed infants. To test this hypothesis, we have planned and conducted an open prospective randomized nutritional intervention study.

Aim of the study

The aim of our study was to evaluate the effect of feeding with a standard infant formula enriched with the specific mixture of oligosaccharides (scGOS/lcFOS; 9:1; 8 g/L) compared to a formula without oligosaccharides and breastfeeding during the first months of life on digestive system local immunity and further development of allergic and infectious diseases in young children.

Materials and methods

Two hundred and forty healthy term newborns were involved into the study on its first stage. Depending on the type of feeding the infants were divided into 3 groups (with random (sealed envelope randomization) allocation to one of the formula feeding groups): the group 1 included 80 infants who were breastfed, the group 2 – 80 infants consuming the formula supplemented with a specific mixture of oligosaccharides, and the group 3 – 80 infants fed

with a standard formula (Fig. 1). Enrollment into the second and the third groups took place only if mothers had decided not to breastfeed. Infants were supposed to be breastfed or fed with the allocated formula for at least 2 months.

Babies in the groups did not differ by age at the enrollment, gender, physical and social settings. Participation in the study was voluntary with signing of informed consent by parents. This study was approved by a local Ethics Committee.

Inclusion criteria were:

- Healthy term newborns with birth weight >2500 g appropriate for gestational age.
- Apgar scores >7.
- Uncomplicated early course of neonatal period.
- Impossibility of breastfeeding (for infants randomized into the bottle-feeding groups).
- Informed consent was signed by parents.

Exclusion criteria:

- The minimum possibility of breastfeeding (for infants randomized into the bottle-feeding groups).
- Administration of probiotics and prebiotics before involvement into the study.

Growth parameters (weight, length, head circumference, and BMI) were determined at enrollment, in 2 and at 18 months.

Saliva and fecal samples were taken on the day of inclusion into the study and after 2 months of exclusive feeding with the selected formula or breast milk. Saliva sIgA (sIgA ELISA «Khemо-Medica» Ltd), alpha-defensins HNP1-3 (HNP 1-3 ELISA KIT) and fecal lysozyme (Human LL-37 ELISA TEST KIT) were determined by an ELISA method. Gut microbiota composition was assessed in 2 months after beginning of the study using standard bacteriological methods. Bifidobacteria, Lactobacilli and Candida fungi have been analyzed.

By the end of the second phase of the study, we compared the cumulative incidences of atopic dermatitis (AD), obstructive bronchitis, recurrent wheezing, gastrointestinal and upper respiratory tract infections (URTI) at 18 months depending on type feeding in the first months of life.

AD was diagnosed according to the criteria described by Harrigan and Rabinowitz [10] and Muraro et al. [11]. The diagnosis of AD was confirmed if the following features were detected: pruritus, involvement of the face, skull facial, and/or extensor part of the extremities, and a minimal duration of the symptoms of 4 weeks. Recurrent wheezing was defined as 3 or more physician-diagnosed wheezing episodes [13]. Official medical documents and reports were used.

By the end of the study, the number of children in groups decreased (Fig. 1). The main reasons for dropping out were failure to follow up, poor compliance, change of feeding type, for example, lack of breast milk or replacement of the preselected formula in the bottle-fed groups.

Statistical analysis

Standard methods of descriptive, comparative and categorical analyses were used. If normally distributed continuous

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