Study objective/Hypothesis

The purpose of the study is to find out which of the factors have a critical influence on the rate of development of a food allergy in children with cow's milk allergy (the age of food allergy manifestation, the type of milk-free diet, the addition of probiotics to modified milk, the type of allergic reaction, the type of affected organ, the size of milk allowance triggering an allergic reaction in a food challenge test, family history of allergy/atopy, a child's other allergic diseases, blood concentration of cow's milk protein specific antibodies, SPT and APT results).

Research method

The study group will include 0-12-month-old infants living in the region of West Pomerania. The study will cover 200 infants (study group) allergic to cow's milk protein (CMPA: Cow's Milk Protein Allergy): IgE-mediated (100 subjects) and non IgE-mediated (100 subjects). The control group will consist of 50 infants suspected of CMPA whose cow's milk challenge has proved to be negative. They will be controlled over the period not shorter than 24 months in terms of: the evaluation of their physical development, immunological parameters and the nutritional value of their diet. The criterium for a child to participate in the study group will be diagnosed CMPA and their parent's/caretaker's consent to a child's participation in a controlled trial. The criterium for a child to participate in the control group will be elimnated CMPA and any other chronic disease (including immune system disorders) and their parent's/caretaker's consent to a child's participation in a controlled trial.

CMPA (both the IgE-mediated and non IgE-mediated) will be diagnosed on the basis of the open food challenge test. All the children will be allergologically and immunologically tested. Titres will be determined from 0,5 ml of blood serum collected during other diagnostic procedures (blood count).

Following the CMPA diagnosis the continuation of breastfeeding (by mothers remaining on milk-free diet) or a milk-free diet with a formula advised before in outpatient settings will be recommended. The condition for continuing the existing diet treatment will be its good tolerance and subsided CMPA symptoms. In the case of those children whose diet treatment will be implemented following the CMPA diagnosis, the milk-replacement formula will be chosen on a random basis.

Follow-up food challenges will be performed every 6-12 months. At the same time control allergological and immunological tests will be taken. The evaluation of a child's physical development will be performed basing on the measurement and appraisal of: their body mass, height, head circumference as well as age-adequate major and minor motor skills. Their anthropometric parameters will be related to the growth charts appropriate for the subjects' age and sex. Factors determining the rate of allergy development in children allergic to cow's milk protein will be assessed and analysed.

Milk-replacement formulas will be evaluated in terms of their enery value and the content of elementary nutrients as well as additional ingredients (omega-3 long-chain polysaturated fatty acids, probiotics). Nutritional value of the applied milk-replacers will be related to nutrition standards developed for the children in the control group.

The results of the study will be statistically processed and then publicised (scientific conferences, publications in journals from the IF list).

Study impact

The study findings will make it possible to recognise and verify factors that are responsible for the changes in the cow's milk protein specific antibodies titres in the absence of the body exposition to the allergising fractions of cow's milk proteins. That in turn will result in subsiding immune reactions. In addition, we will be able to determine the relationship between the titres of cow's milk protein specific antibodies and the type of a milk-free diet.