

The evaluation of tolerance rate and the immune tolerance acquisition in children with cow's milk allergy switching from amino acid-based formula to extensively hydrolyzed casein formula: the SDACMA project

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Objectives and Study: The **Step down approach** for **cow's milk allergy** (SDACMA) project was designed to evaluate the tolerance rate and the effect of immune tolerance acquisition in CMA children who started dietary treatment with amino acid-based formula (AAF) and switched to extensively hydrolyzed casein formula with the probiotic *L.rhamnosus* GG (EHCF+LGG).

Methods: Double blind randomized trial involving children with IgE-mediated CMA receiving AAF from at least 4 weeks with full and stable symptoms remission. The EHCF+LGG tolerance was evaluated by the results of double blind placebo controlled food challenge (DBPCFC). Then, subjects who tolerated EHCF+LGG were randomly allocated to two groups of 12-m dietary intervention: group 1, continuing AAF, and group 2 receiving EHCF+LGG. Immune tolerance acquisition was evaluated after 12 months of dietary treatment by the result of DBPCFC.

Results: 60 IgE-mediated CMA children were enrolled [55% male, mean age (\pm SD) at CMA diagnosis 4 (\pm 1.3) months]. 59 out of 60 patients were able to tolerate EHCF+LGG. These patients were randomly allocated into the two groups of dietary intervention. At the enrollment demographic and anamnestic features were similar into the two groups [Group 1: 53.3% male, mean age (\pm SD) at CMA diagnosis 3.9 (\pm 1.3) months; symptoms at CMA diagnosis: 66.7% gastrointestinal, 80% cutaneous, 13.3% respiratory. Group 2: 58.6 % male, mean age (\pm SD) at CMA diagnosis 4.2 (\pm 1.2) months; symptoms at CMA diagnosis: 75.9% gastrointestinal, 65.5% cutaneous, 10.3% respiratory]. After 12-mof dietary treatment, the rate of immune tolerance acquisition was higher in the EHCF+LGG group if compared to the AAF group (48.3% vs 3.3%, $p < 0.001$).

Conclusions: The results of the SDACMA project suggest that EHCF+LGG could be tolerated by the vast majority of the IgE-mediated CMA children and that, when possible, the step down from AAF to EHCF+LGG could result in a higher rate of immune tolerance acquisition after 12-m of dietary treatment.

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