Summary

Study title: **Treatment with Omalizumab in food allergic children (TOFAC)**

EudraCT: 2018-004427-37

The study was premature ended at 15-03-2022 after screening of 40 children and inclusion of 23 children.

The recruitment was affected by the COVID-19 pandemic and the many visits that the children should attend. Before early termination statistical calculations for the outcome were performed and sufficient power was expected using different assumptions for outcome.

The study evaluated the efficacy of Omalizumab on food allergy thresholds in children with severe food allergy. Children between 6 and 18 years with a clinical diagnosis of food allergy to ≥1 food allergen, including a positive SPT (mean wheal diameter $\geq$ 3 mm), s-IgE $\geq$ 0.35 kIU/l to the allergen in question, and a positive food challenge with a threshold at or below 300 mg of protein (443 mg cumulative) in a double blind placebo controlled food challenge (DBPCFC). A DBPCFC was performed at entry and after 3 and 6 months of treatment. Skin tests and blood samples were performed before entry, after 3, 6 and 9 months. Eligible participants was randomized to treatment with Omalizumab (asthma dosing according to total IgE and weight) or placebo (3:1). By randomization 17 (6-16 years) were randomized to active and 6 (7-17 years) to placebo; 20 were evaluable after 3 months of treatment (primary endpoint) and 18 after 6 months of treatment, and 18 were evaluated at 9 months (3 months after the last treatment).

No serious adverse event or suspected unexpected serious adverse reactions were registered. Infections were seen in both groups. One child developed mild, localized urticaria possible drug related after one treatment but not thereafter.

A significant improvement in threshold was seen in the Omalizumab group compared to placebo at 3 months (primary outcome). The results will be published in 2023.

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