INTO-study – Randomized controlled study on the INduction of TOlerance in babies
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Aims: This general population based RCT aims at answering two major hypotheses: First, systematic early introduction of solid foods decreases the incidence of food allergy and dietary restrictions by the age of one year. Second, stimulation with the symptom-eliciting food rather than avoidance will induce tolerance in babies with non-severe allergic symptoms.

Methods: All new born babies living in the city of Oulu are recruited to the study (n=1380) at their first health nurse visit (at or before 1 month of age) in the local primary care child health clinics. Families in the intervention group will get an instruction booklet including information on early systematic introduction of solid foods starting at the age of 4 months, with foodstuff from all major groups in diet by the age of 6 months (vegetables and fruits, wheat and other grains, meat, fish, egg, dairy products). Furthermore, the booklet includes information and instructions on food related symptoms and atopic eczema. Babies with mild symptoms are encouraged to continue the symptom-eliciting food. All families fill out monthly internet-based questionnaires on food diary, symptoms, diagnoses and health care visits until the age of 1 year. Dietary restrictions and food allergy diagnoses are verified at the age of one year. The primary outcome measures will be the incidence of diet restrictions, parent-reported and doctor-verified food allergies and atopic eczema by the age of 1 year. The secondary outcomes will be the need for health services and the family experienced distress during the first year of life.

Results: The study has started in March 2014. Currently, 1317 babies have been recruited and 645 children have completed the entire study by the end of April 2016. According to the preliminary data from questionnaires at the age of 6 months, 70.6% of 425 children in the intervention group and 74.1% of 444 children in the control group were still on breast-feeding (p=0.256). Furthermore, 45.9% of children in the intervention group and 23.3% in the control group (p<0.001) had 2 or more potentially allergenic food (wheat, egg, fish or fermented milk products) in their diet before the age of 6 months.

Conclusion: The study protocol seems to be feasible at a population level and does not affect the rate of breastfeeding during the first 6 months of babies. INTO-study will provide invaluable data on early-feeding strategy in primary and secondary prevention of food allergy.