

Paula Kauppi

Study protocol

19 Oct 2012

- The effect of per oral immunotherapy treatment in severe IgE mediated egg, milk and nut allergy in adults.

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Summary

Prospective study on per oral immunotherapy treatment in IgE mediated egg, milk and nut allergy in adults (18-50- year olds).

1. Aims

We aim to analyse the results of per oral immunotherapy treatment in severe egg, milk and nut allergy in adults.

Could severe egg, milk and nut allergy be treated with oral immunotherapy treatment in stead of total allergen avoidance and could desensitization thus be achieved?

2. Study plan

2.1. Subjects

We study up to 90 subjects. All subjects are adults having no other severe chronic diseases. The subjects belong to four different groups:

- (a) **30** 18-50 year olds who start per oral immunotherapy treatment in severe egg allergy.
- (b) **30** 18-50_year olds who start per oral immunotherapy treatment in severe milk allergy.

- (c) **30** 18-50 year olds who start per oral immunotherapy treatment in severe nut allergy.

The diagnosis of milk or egg allergy is verified with positive history, skin prick test, allergen specific IgE antibodies. In addition, food allergy is verified with an allergen specific challenge test.

Atopic subjects may have simultaneously other allergies. Intermittent mild asthma, and mild and moderate persistent asthma are tolerated and treatment with inhaled steroids and other asthma medication is allowed. Atopic subjects may have additional skin symptoms. Quality of life, anxiety and patient history data is collected by questionnaires. All patients undergo a spirometry with a bronchodilator test, exhaled nitric oxide and a methacholine challenge before and a year after oral immunotherapy. Those with test results diagnostic for asthma (FEV1 response in a bronchodilator test > 12%/200ml and/ or PD20 <600 µg/ml methacholine in methacholine provocation test) are treated with asthma medication before hyposensibilisation treatment is started.

Exclusion criteria: adults with instable cerebrovascular or heart disease, active autoimmune disease or cancer, or use of betablocking agents. In addition, poorly controlled asthma or FEV1 < 70% are not tolerated.

2.2. Allergen specific challenge test

Increasing doses are given every 60 minutes during the food allergen challenge. After the last dose, patients are observed at least for 2 hours. The protocol is done in a double-blind manner (day A, day B) in peanut and egg allergy and in one-day open manner in milk allergy.

2.3. Study protocol

Increasing doses are given daily. The first dose is given at the hospital and observed. Pre-specified other doses are also given observed at the hospital but otherwise oral food immunotherapy is continued at home.

All the patients undergoing oral immunotherapy are prescribed with emergency medication such as antihistamine tablets, prednisolon tablets (40mg for three days in adults), epinephrine autoinjector (300 µg per dose) and salbutamol or terbutaline inhalator.

After escalating doses of allergen during the first phase of oral immunotherapy, the treatment is continued with the highest tolerated maintenance dose until one year of therapy. Spirometry with a bronchodilator test, exhaled nitric oxide, a methacholine challenge and immunological parameters are studied a year after oral immunotherapy.

2.4. Immunological parameters

Serum samples are taken for allergen specific and allergen component evaluation (IgE) before oral immunotherapy and at one year after starting the therapy.