The effects of plant stanols on the immune function of asthma patients

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The major research objective is to prove that the consumption of plant stanol ester enriched yogurts can improve immune function in vivo in asthma patients

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON36451

Source
ToetsingOnline

Brief title
asthma vaccination study

Condition

- Allergic conditions
- Respiratory disorders NEC

Synonym
allergy, Asthma

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Raisio Benecol Ltd, Raisio, Finland ,Raisio Benecol Ltd;Raisio;Finland

Intervention

Keyword: asthma, immune function, plant stanols, vaccination response

Outcome measures

Primary outcome

Specific anti-HAV antibody titers after vaccination

Secondary outcome

Phagocytic capacity of neutrophils; NK-cell activity; Th1 and Th2 cytokine

production profiles by PHA stimulated PMBCs.

Study description

Background summary

Plant stanols are well known for their effects on lowering intestinal cholesterol absorption ultimately resulting in 10-15% reduced serum LDL cholesterol concentrations in humans. In addition we have also shown that serum triacylglycerol (TG) concentrations may be lowered in subjects with elevated baseline concentrations. Till now, there is little evidence for plant stanol effects other than improving lipid profiles. However, we have very recently found strong indications in ex vivo models using isolated human peripheral mononuclear blood cells (PBMCs) from healthy volunteers that plant stanols have the capacity to improve immune function. More into detail, plant stanols shifted the differentiation of naive T-cells into the Th1 direction by activating a specific receptor present on the Antigen presenting cells (APCs) and T-cells. This effect might ultimately be helpful in situations in which the Th1/Th2 cell balance is disturbed into a Th2 over-responsiveness. By activating the Th1 response, the disturbed balance may be restored. This is for example a possibility in the treatment or prevention of asthma, food allergies or HIV in susceptible subjects. In addition, very recently (MEC 08-3-051) we also showed these ex vivo Th1 stimulating effects of plant stanols specifically in PBMCs isolated from asthma patients, as said, a condition characterized by a Th2 dominant immune response.

Study objective

The major research objective is to prove that the consumption of plant stanol

ester enriched yogurts can improve immune function in vivo in asthma patients

Study design

A double-blind randomized placebo-controlled human intervention study in which 90 patients with clinically proven asthma will participate: 45 in the intervention group receiving plant stanol yoghurt and 45 in the control group receiving a control yoghurt without added plant stanols. At the end of the run-in period as well as at the end of the experimental period blood will be sampled to isolate PBMCs. These cells are used to evaluate effects on cytokine production, phagocytic capacity of neutrophils, and the activity of NK cells. In addition, during the experimental period all subjects receive a vaccination against Hepatitis A Virus. After 1, 2, 3, and 4 weeks blood will be sampled to monitor specific immunoglobulin titers to HAV.

Intervention

During the first two weeks of the study (the run-in period) all participants receive control yoghurts without added plant stanol esters. Directly after these two weeks, the intervention period starts, which lasts eight weeks. During this period 45 participants continue to use the control yoghurts, and 45 participants switch to the consumption of plant stanol ester enriched yoghurts.

Study burden and risks

During the study, 9 blood samples (each 20 or 50 mL) will be taken. Total time investment for the subjects will be 160 min. Occasionally, a heamatoma or bruise can occur during venipuncture. After the vaccination a heamatoma or a sore arm can occur. These side effects should disappear within 4-5 days. Other common side effects are headache, loss of appetite, and fatigue, which usually will disappear within 24 hours. The results of this study will show whether consumption of plant stanol enriched yogurts is able to restore the disturbed th1/Th2 balance in asthma patients. This is expected to reduce asthmatic exacerbations, as the Th2 dominant immune response seems causal to asthmatic symptoms.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Asthma Age between 18 and 70 Men and women Specific anti-hepatitis A virus antibody titers < 20 IU/L

Exclusion criteria

- Current asthmatic exacerbations, i.e. use of prednisone or pneumoia - Other immune-related pathology, e.g. autoimmune diseases, diabetes, HTLV, HIV, other inflammatory diseases than asthma. - Previously being vaccinated against hepatitis A - Pregnancy or lactation - Impaired liver and kidney function - Use of immunosuppressive medication - Allergy to neomycin - Throbocytopenia

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2010
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	21-06-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	11-04-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL32663.068.10