Immunomodulatory effects of Inulin-type fructans in a hepatitis B vaccination study.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21512

Source
Nationaal Trial Register

Health condition

vaccination response to hepatitis B

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG)
(The Netherlands)
Source(s) of monetary or material Support: Top Institute Food and Nutrition, Carbohydrate Competence Center

Intervention

Outcome measures

Primary outcome

Vaccination titer response to hepatitis B.

Secondary outcome

Changes in immune cell populations, fecal IgA and short chain fatty acids and microbiota composition.

Study description

Background summary

Rationale:

Inulin-type fructans (ITFs) are dietary fibers which have beneficial effects on general health, including the immune system. These fibers are part of our daily diet and can be found in chicory roots or sugar beets. ITFs are digested in different molecular weights and have been described to stimulate the bacteria in our gut (microbiota) and to modulate the immune system. How this beneficial effect of ITFs occurs is not known but high fiber intake is well known for its positive effects on digestion and is associated with lower mortality in subjects suffering from circulatory, digestive, and non-cardiovascular noncancerous inflammatory diseases. We recently showed that beneficial health effects may be related to effects of ITFs on so-called pattern recognition receptors (PRRs) on immune cells. These PRRs are sensors of the immune system and determine whether a stimulation or inhibition of the immune system occurs when they bind to molecules such as fibers. We found that the effect of ITFs on PRRs was dependent on the molecular weight of the ITFs with a more stimulating effect with high molecular weight ITFs and a more regulatory (or inhibiting) effect with ITFs with a lower molecular weight. To confirm that this also occurs in vivo, we asked students during their life-science education in immunology to enrich their diet with these fibers. We found a stimulation of immunity by an enhancement of the T helper 1 (Th1) cells, as well as an increase in regulatory T cells. This made us hypothesize that ITF enrichment in diets may enhance vaccination efficacy.

A vaccination protocol that may benefit from stimulation of immune responses by ITF supplementation is hepatitis B vaccination. This vaccination protocol requires three boosts in order to reach safe antibody titers. In this study we therefore propose to perform an ITF fiber supplementation around an already existing hepatitis B vaccination program to determine whether ITF intake improves immune function.

Objective:

Main objective is to study the effects of ITF supplementation (low and high molecular weight) on the efficacy of a hepatitis B vaccination in students of Life-sciences and Medicine. The vaccinations are a mandatory part of their bachelor training when they start to work with human material. We will study vaccine-induced antibody titers, and secondary objectives are to study modification of relevant immune cell populations in peripheral blood and fecal parameters. In fecal samples, Short Chain Fatty Acids (SCFA), and levels of ImmunoglobulinA

(IgA) will be analyzed, as well as the bacterial composition of the microbiota.

Study design:

Double-blind randomized placebo controlled intervention study.

Study population:

Healthy Caucasian male third year students of llife-science and Medicine in the ages between 20-30 yr. old, 12 subjects per experimental group, in total 36 subjects.

Intervention:

This study comprises 3 experimental groups in total; I) supplementation with 8g/d low molecular weight ITF (Frutafit®CLR) + hepatitis B vaccination, II) supplementation with 8g/d high molecular weight ITF (Frutafit®TEX!)+ hepatitis B vaccination, III) supplementation with 8g/d placebo (fructose) + hepatitis B vaccination.

Main study parameters:

Vaccine-specific antibody titers, peripheral blood immune cell populations, microbiota, and SCFA profiles and IgA levels in feces.

Study objective

Inulin-type fructans stimulate hepatitis B vaccination response.

Study design

T=0: Start dietary intervention, basal blood sample, basal fecal sample;

T=7d: Vaccination, blood sample, fecal sample;

T=14: End of dietary intervention, blood sample, fecal sample;

T=21: Blood sample, fecal sample;

T=28: Fecal sample;

T=35: Blood sample, fecal sample.

Intervention

The study population will consist of healthy Caucasian male volunteers (age 20-30 yrs.), all receiving food grade ITFs; Frutafit®CLR, Frutafit®TEX! or a placebo (fructose). All in combination with the first shot of the annual hepatitis B vaccination received by these volunteers during their bachelor at the Medical Faculty of the UMCG. The vaccination program is organised by the UMCG and the coordinator, dr. Lidia Westers, was contacted and asked to give information letters and enrollment forms to the students signing up for hepatitis B vaccination. This will lead to 3 experimental groups in total; I) Frutafit®CLR+hepatitis B vaccination, II) Frutafit®TEX!+hepatitis B vaccination, III) placebo (fructose)+hepatitis B vaccination. Blood samples (lithium heparin) will be collected at day 0, 7, 14, 21, and 35. Fecal samples will be collected once a week starting at day 0 until day 35.

Contacts

Public
University Medical Center Groningen (UMCG)
Pathology and Medical Biology
section Immunoendocrinology
Hanzeplein 1, EA 11
P. Vos, de
Groningen 9713 GZ
The Netherlands
+31 (0)50 3611045
Scientific
University Medical Center Groningen (UMCG)
Pathology and Medical Biology
section Immunoendocrinology
Hanzeplein 1, EA 11
P. Vos, de
Groningen 9713 GZ
The Netherlands
+31 (0)50 3611045

Eligibility criteria

Inclusion criteria

1. Age 20-30 yr;

2. Healthy subjects;

3. Male subjects;

4. Written informed consent;

5. Caucasian subjects;

6. Caucasian males;

7. Hepatitis B vaccination;

8. Subjects exposed to patient material;

9. Subjects occupied within the UMCG.

Exclusion criteria

1. Presence of acute or chronic diseases;

2. Gastrointestinal disorders (e.g. inflammatory bowel disease, celiac disease);

3. Gastrointestinal surgery;

4. Treatment with antibiotics within 6 months of the start of the study;

5. Prior vaccination with hepatitis B;

6. Previous hepatitis B infection;

7. Immunodeficiencies;

8. Use of anti-coagulant drugs.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	36
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 41596
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3801
NTR-old	NTR3974
CCMO	NL41644.042.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41596

Study results

Summary results
N/A