Bovine Osteopontin for Elderly Immune Support

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Assess the percentage of responders to hepatitis B vaccination (i.e. attaining anti-hepatitis B antibody titres beyond 10 IU/L) in healthy elderly receiving a daily dose of OPN-10, compared to a placebo product.Secondary objectives:• Compare the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53888

Source
ToetsingOnline

Brief title
BOFEI Study

Condition

- Other condition

Synonym
immune support, vaccination response

Health condition

immune modulation in healthy subjects

Research involving
Human

Sponsors and support

Primary sponsor: ARLA Foods Ingredients Group P/S
Source(s) of monetary or material Support: by Arla Foods Ingredients Group

Intervention

Keyword: bovine osteopontin, elderly, immunity, vaccination response

Outcome measures

Primary outcome

• Anti-hepatitis B antibody titre

Secondary outcome

• Serum cytokines

• Plasma OPN (bOPN and hOPN)

• Plasma LBP

• Symptoms of respiratory infections

• Clinical chemistry and hematology

• Serum P1NP and CTX1

Study description

Background summary

Osteopontin (OPN) is a phosphorylated glycoprotein that is present in human milk and bovine milk. It is involved in immune function. Lacprodan® OPN-10 is a protein fraction isolated from bovine milk which is rich in OPN. In infants, supplementation with Lacprodan® OPN-10 is well tolerated, with clinically proven immunomodulatory outcomes such as downregulation of inflammatory cytokines and increases in T-cells and monocytes. Potential effects of Lacprodan® OPN-10 in adults and elderly have not yet been studied. During aging, the immune system undergoes profound decline, and specifically the responsiveness of the Th1-response is attenuated. The current study design therefore aims to investigate the potential immune effects of Lacprodan® OPN-10

in elderly.

Study objective

Assess the percentage of responders to hepatitis B vaccination (i.e. attaining anti-hepatitis B antibody titres beyond 10 IU/L) in healthy elderly receiving a daily dose of OPN-10, compared to a placebo product.

Secondary objectives:
• Compare the changes in serum anti-hepatitis B antibody titres between treatment groups
• Compare the change in circulating cytokines between treatment groups
• Quantify plasma levels of human and bovine OPN at baseline, and after intervention
• Determine whether intake of OPN-10 affects plasma levels of human OPN.
• Compare the change in serum LPS binding protein (LBP) between treatment groups
• Compare the incidence of infections during the trial, including specific upper and lower respiratory tract infections, between treatment groups
• Assess the safety of the selected intervention dose, including effects on markers of bone remodelling

Study design

double-blind, randomized, placebo-controlled trial, with two parallel treatment arms

Intervention

The active treatment consists of Lacprodan OPN-10, in the form of sachets, in a dose of 2.5 g/day for subjects <70 kg and 3.2 g/day for subjects >=70 kg. The sachets will be taken twice a day, with a meal.
The placebo treatment consist of sachets in which Lacprodan® OPN-10 is replaced by maltodextrin. Total duration of the intervention is 14 weeks.

Study burden and risks

The subjects will not benefit directly from participation in this study, apart from receiving a subject fee for their time investment plus reimbursement of traveling expenses.

Lacprodan® OPN-10 has a positive novel food evaluation by EFSA and a GRAS notification, and hence is considered safe

The burden imposed by study procedures includes the daily intake of the study product, the (7) visits to the research location, the blood sampling (at 6 visits), faecal sample collection (3 times) and the vaccination injection (3

times). The collection of blood samples may produce discomfort or minor bleeding and the possibility of bruising at the site of the needle puncture. There is also a slight risk of infection at the site of the needle puncture.
Side effects of hepatitis B vaccination that are reported to occur often or very often are: loss of appetite, irritability, headache, gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea, abdominal pain), pain and redness at the injection site, fatigue, fever, malaise. Less common side effects include dizziness, myalgia, and influenza-like symptoms.
Overall, the risks associated with participation in this study are considered small.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

• Age >=60 and healthy

• Self-reported regular Dutch eating habits as assessed by questionnaire (3 main meals per day)
• Anti hepatitis B antibody titer <= 4 IU/L, no prior hepatitis B vaccination or infection
• Non-smokers
• BMI 22-30
• In good health as assessed during screening, and the medical investigator*s professional judgment
• Adherence to habitual diet, no changes during study period
• Signed informed consent
• Ability to follow Dutch verbal and written instructions
• Willing to accept disclosure of the financial benefit of participation in the study to the authorities concerned
• Willing to accept use of all encoded data, including publication, and the confidential use and storage of all data for at least 15 years
• Willing to comply with study procedures, including intake of study products and collection of stool and blood samples
• Willingness to give up blood donation starting at run-in and during the entire study

Exclusion criteria

• Prior HB vaccination or infection
• Any vaccination in the past month or any scheduled vaccination during the study period
• Acute infection in the past month
• Treatment with oral antibiotics within 2 months of the start of the study,
• Serious progressive disease or non-stabilized chronic illness (e.g., diabetes mellitus, cardiac insufficiency, respiratory insufficiency, cancer, chronic kidney or liver disease)
• History of cancer
• Gastrointestinal disorders (e.g., inflammatory bowel disease)
• Immunodeficiency disorder
• Use of immunosuppressive drugs (e.g. cyclosporine, azathioprine, systemic corticosteroids, antibodies)
• Allergy or hypersensitivity to milk proteins, or lactose intolerance
• Unexplained weight loss or weight gain of > 3 kg in the 3 months prior to pre-study screening
• Evidence of current excessive alcohol consumption (>4 consumptions/day or >20 consumptions/week) or drug (ab)use
• Mental status that is incompatible with the proper conduct of the study
• Not having a general practitioner, not allowing disclosure of participation to the general practitioner or not allow to inform the general practitioner about abnormal results.
• Participation in any clinical trial including blood sampling and/or

administration of substances starting 1 month prior to study start and during the entire study.
• Personnel of NIZO or ARLA, their partner and their first- and second-degree relatives.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-02-2023
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	29-08-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	14-11-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	12-01-2023

Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	07-04-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL81499.028.22