Effect of a probiotic strain on immune response to influenza vaccination

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To investigate the effect of Bifidobacterium lactis CECT 8145 BPL1® on the seroconversion rate after influenza vaccination in healthy adults, compared to placebo treatment.

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

Summary

ID

NL-OMON51538

Source
ToetsingOnline

Brief title
VERB Study

Condition

- Other condition

Synonym
immune support, vaccination response

Health condition

immune modulation in healthy subjects

Research involving
Human

Sponsors and support

Primary sponsor: ADM Biopolis
Source(s) of monetary or material Support: by industry: ADM Biopolis

Intervention

Keyword: immune function, probiotic, vaccination response

Outcome measures

Primary outcome

The percentage of subjects with either a pre-vaccination HAI titer < 1:10 and a post-vaccination HAI titer >= 1:40 or a pre-vaccination HAI titer >= 1:10 and a minimum four-fold rise in post-vaccination HAI antibody titer.

Secondary outcome

• Geometric Mean Titre of influenza-specific antibodies

• Seroprotection

• Change in plasma cytokines (IL-10, IL-4, and TNF-alpha, IFN-gamma)

• Vaccine-specific plasma IgG concentrations

• Plasma total IgG concentrations

• Symptoms of respiratory tract infections (RTI)

• Gastrointestinal symptoms

• Adverse Events

Study description

Background summary

Vaccination response may be enhanced by oral supplementation with specific probiotic strains. Preclinical study results for Bifidobacterium lactis CECT 8145 BPL1® indicate that this strain might be a good candidate for enhancement of vaccine response. Influenza viruses are an important cause of respiratory infections; influenza vaccination response in general is suboptimal. Intake of BPL1® might contribute to enhanced influenza vaccination response and increased resistance to infection. This is to be investigated in a human intervention

trial with this specific probiotic strain.

Study objective

To investigate the effect of Bifidobacterium lactis CECT 8145 BPL1® on the seroconversion rate after influenza vaccination in healthy adults, compared to placebo treatment.

Study design

The study is designed as a double-blind, randomized, placebo-controlled trial, with two treatment arms. After a 2-week intervention period, all subjects will receive an influenza vaccination.

Intervention

The active intervention group will receive Bifidobacterium lactis CECT 8145 BPL1® (BLP1®), as a food supplement. The placebo group will receive a supplement in which BLP1® is replaced by maltodextrin, but indistinguishable in appearance and taste. Interventions will be administered for a total of 6 weeks (42 days).

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. In case they are exposed to the influenza virus, after their participation in the study, they may experience a benefit from the influenza vaccination.
Potential risks could be related to a) study product, b) study procedures or c) non-investigational product (influenza vaccination).
The probiotic study product BPL1® is widely marketed in Europe, North and South America and Asia. There are no reported safety concerns for BPL1®.
The burden imposed by study procedures includes the daily intake of the study product, the (4) visits to the research location, the blood sampling (at 3 visits), and the vaccination injection. 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 flu vaccination that are reported to occur more often are redness and pain on the injection site. In 10-30% of the vaccinated population, flu-like symptoms such as headache, muscle soreness, irritability or reduced appetite are reported, and in a few cases also mild fever and fatigue, for 1-2 days. 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
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

1. Age >=16 and <=65
2. Self-reported regular Dutch eating habits as assessed by questionnaire (3 main meals per day)
3. Non-smokers (ex-smokers can participate if they stopped at least 6 months before screening)
4. BMI >=18.5 and <=28
5. In good health as assessed during screening, and the medical investigator*s professional judgment
6. Adherence to habitual diet, no changes during study period
7. Signed informed consent

Exclusion criteria

1. Influenza vaccination within 6 months before the start of the intervention
2. Any vaccination in the month before randomization (visit 1) or any scheduled vaccination during the study period
3. Self-reported influenza infection within 6 months before the start of the intervention
4. Acute infection (including gastroenteritis) within 2 months before start of the intervention
5. Treatment with oral antibiotics within 2 months before the start of the intervention
6. Serious progressive disease or non-stabilized chronic illness (e.g., diabetes mellitus, cardiac insufficiency, respiratory insufficiency, cancer, chronic kidney or liver disease)
7. Gastrointestinal disorders (e.g., inflammatory bowel disease)
8. Immunodeficiency or autoimmune disorder
9. Use of immunosuppressive drugs (e.g. cyclosporine, azathioprine, systemic corticosteroids, antibodies)
10. Unexplained weight loss or weight gain of > 3 kg in the 3 months prior to pre-study screening
11. Evidence of current excessive alcohol consumption (>4 consumptions/day or >20 consumptions/week) or drug (ab)use
12. No change in use of immune boosting supplements during the study
13. Mental status that is incompatible with the proper conduct of the study

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):	24-01-2023
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	05-12-2022
Application type:	First submission
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	NL82666.028.22