Change in markers of immune function associated with Bacillus subtilis CU1 intervention in different age groups

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Primary objective: Explore, quantify and interpret the effect of 4-week intervention with 2 x 109 spores of BSCU1 on fecal sIgA, in healthy adults, elderly and 3-6 year old children.Secondary objectives:Explore, quantify and interpret the effect of...

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

Summary

ID

NL-OMON51589

Source
ToetsingOnline

Brief title
BSCU1 and immune function

Condition

- Other condition

Synonym
immune system

Health condition

normal immune response

Research involving
Human

Sponsors and support

Primary sponsor: Gnosis by Lesaffre
Source(s) of monetary or material Support: Funding by Gnosis by Lesaffre

Intervention

Keyword: immune function, mechanism of action, probiotic

Outcome measures

Primary outcome

- Change in fecal sIgA concentration after 4 weeks intervention, compared to baseline

Secondary outcome

- Change in fecal sIgA concentration after 2 weeks intervention, compared to baseline

- Change in the following markers of immune function, after 4 weeks intervention, compared to baseline, in healthy adults and older subjects:

* Serum cytokine levels (in elderly only)

* Ex vivo cytokines concentration in (LPS-) stimulated and unstimulated whole blood

* Ex vivo phagocytosis in whole blood (using flow cytometry), expressed as % of positive monocytes, % positive granulocytes, mean fluorescence intensity monocytes, and mean fluorescence intensity granulocytes

Study description

Background summary

Limited data from clinical studies indicate that the probiotic strain Bacillus

subtilis CU1 may be effective in reducing common infections. To further support a beneficial effect of BSCU1 on immune function and resistance to infections, additional clinical studies are required. However, relatively little is known as yet with regard to the mechanism of action. More insight into such mechanisms will help to select the most appropriate study design, target population and outcomes in future controlled intervention studies. Therefore, the current study aims to explore a range of possible pathways by which BSCU1 could beneficially modulate the immune system, in three target populations representing the general population.

Study objective

Primary objective: Explore, quantify and interpret the effect of 4-week intervention with 2 x 109 spores of BSCU1 on fecal sIgA, in healthy adults, elderly and 3-6 year old children.
Secondary objectives:
Explore, quantify and interpret the effect of 2-week intervention with 2 x 109 spores of BSCU1 on fecal sIgA, in healthy adults, elderly and 3-6 year old children.

Explore, quantify and interpret the change in the following markers of immune function, after 4 weeks intervention with 2 x 109 spores of BSCU1, in healthy adults and older subjects:
* Serum cytokine levels (in elderly only)
* Ex vivo production of cytokines by (LPS-) stimulated whole blood
* Ex vivo phagocytosis in whole blood

Study design

Single-arm study with repeated measures, involving three different populations, in which each subject serves as its own control

Intervention

All subjects will receive (the content of) one capsule of BSCU1 (containing 2 x 10^9 spores) once daily, for 4 weeks.

Study burden and risks

Parents of the participating children will be invited for 1 screening and 3 site visits, the children will be asked to come to the screening visit for assessment of height and weight and to the final visit. Parents will collect fecal samples from their child at 3 timepoints, bring these to the clinical site, and answer questions on fecal consistency, study product intake and wellbeing. No invasive measures will be performed. The study product is on the market in the EU and in the US, and has been approved for children in this age

category. To obtain insight in the immune stimulatory effect in this specific age group, data need to be collected in this age group and compared with data from other age categories.
Adults/elderly will attend 1 screening visit and 3 site visits. Fasting blood samples will be collected at 1 timepoint during 2 site visits. The total amount of blood collected is 45 ml per visit. Fecal samples will be collected at 3 timepoints and brought to the clinical site. Participants will answer questions on fecal consistency, study product intake and wellbeing at each site visit.

Contacts

Public
Gnosis by Lesaffre

Rue Gabriel Péri 137
Marq-en-Baroeul 59700
FR
Scientific
Gnosis by Lesaffre

Rue Gabriel Péri 137
Marq-en-Baroeul 59700
FR

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Adults:

Substantial
• 30 <= age <= 49 years
• BMI >= 18.5 and <=25 kg/m2
• In good health as assessed during screening (by questionnaire), and the medical investigator*s professional judgment
• Non-smoking

Elderly:
Substantial
• 65 <= age <= 79 years
• BMI 22.0 - 28.0 kg/m2
• Generally healthy as assessed during screening (by questionnaire), and the medical investigator*s professional judgment
• Non-smoking

Procedural (both for adults and elderly):
• Ability to follow Dutch verbal and written instructions
• Signed informed consent
• Willingness to give up blood donation during the entire study

Children:
Substantial
• 3 <= age <= 6 years
• Healthy BMI, cut-off points will be used as indicated by JGZ (BMI jongens en meisjes | Voedingscentrum)
• Generally healthy as assessed during screening (by parental anamnesis), and the study physician*s professional judgment

Procedural:
• Parents/caretakers having the ability to follow Dutch verbal and written instructions
• Signed informed consent

Exclusion criteria

Adults and elderly
Substantial
• Chronic illness (e.g., diabetes mellitus, cardiac insufficiency, respiratory insufficiency, cancer, chronic kidney or liver disease),
• Acute infection in the past month
• Gastrointestinal disorders (e.g., inflammatory bowel disease),
• Acute gastroenteritis in the past 2 months
• Any vaccination in the past month
• Treatment with antibiotics within 2 months of the start of the study,
• Regular use of laxative agents

• Immunodeficiency disorder
• Use of immunosuppressive drugs (e.g.cyclosporine, azathioprine, systemic corticosteroids, antibodies)
• Unexplained weight loss or weight gain of > 3 kg in the 3 months prior to pre-study screening
• Regular consumption of probiotics within 1 month before start of the study
• 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

Procedural:
• 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 Gnosis by Lesaffre, their partner and their first and second degree relatives.

Children
Substantial
• Acute respiratory or gastrointestinal or chronic infections
• Chronic systemic or metabolic diseases
• Gastrointestinal disorders (e.g., inflammatory bowel disease),
• Acute gastroenteritis in the past 2 months
• Any vaccination in the past month
• Treatment with antibiotics within 2 months of the start of the study,
• Immunodeficiency disorder
• Use of anti-inflammatory or immunosuppressive drugs (e.g.cyclosporine, azathioprine, systemic corticosteroids, antibodies)
• Regular use of laxative agents
• Regular consumption of probiotic supplements within 1 month before start of the study

Procedural:
• Parents or caretakers not having a general practitioner, not allowing disclosure of participation to the general practitioner or not allowing to inform the general practitioner about abnormal results.
• Participation in any clinical trial starting 1 month prior to study start and during the entire study.
• Parents who are personnel of NIZO or Gnosis by Lesaffre, their partner and their first and second degree relatives.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-05-2022
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	08-04-2022
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL79890.000.21