A Nutritional intervention study to evaluate the effect Of Bovine Lactoferrin on innate immunity in Elderly people

Published: 15-08-2016
Last updated: 16-04-2024

Aim of the current study is to evaluate the effect of lactoferrin on the innate immune response in elderly in a pilot study. Furthermore, support of this effect by GOS and Vitamin D will be studied.

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

Summary

ID

NL-OMON43339

Source
ToetsingOnline

Brief title
NOBLE

Condition

- Other condition
- Immunodeficiency syndromes
- Viral infectious disorders

Synonym
Immunosenescence, weakening of the immune system

Health condition

ontsteking

Research involving

Human

Sponsors and support

Primary sponsor: FrieslandCampina Nederland BV
Source(s) of monetary or material Support: FrieslandCampina Nederland BV

Intervention

Keyword: Elderly, Immunity, Lactoferrin, Markers of inflammation

Outcome measures

Primary outcome

IFN-a and IL-6 production by PBMCs upon ex vivo TLR7 stimulation.

Secondary outcome

- TNF-a production by PBMCs upon ex vivo TLR7 stimulation

- the percentage IFN-a-, IL-6- or TNF-a-producing pDCs in PBMCs upon ex vivo TLR7 stimulation

The study will have an additional exploratory character, by analyzing the ex vivo PBMC response to various TLR-stimuli. Also other inflammatory markers and markers of osteoarthritis will be measured in serum/plasma.

In case of positive outcomes for any of the 3 dietary subsequent intervention periods, fecal samples will be used for analysis of microbiota, SCFAs, and markers of inflammation and gut barrier function (e.g. calprotectin).

Study description

Background summary

The global healthcare system is challenged by tremendous demographic changes that are occurring worldwide. It is expected that in 2050, 16% of the population is older than 65 years. Because the risk of health issues increases with age, it is important to find ways to keep elderly people healthy. With increasing age, the immune system becomes compromised. Therefore, elderly people are more sensitive to infections, and vaccinations provide insufficient protection. Also diseases associated with chronic inflammation occure more frequently in elderly. It is now generally thought that this is caused by a decreased ability of the immune system to regulate immune responses (Immunosenescence).
It is important to identify ways to support the immune system elderly. One way to achieve this is by food. Lactoferrin is one of the major whey proteins in milk and has been described to have beneficial effects on the immune system and to reduce inflammation. In addition to lactoferrin, galacto-oligosaccharides and vitamin D may also be relevant for support immunity in elderly people.

Study objective

Aim of the current study is to evaluate the effect of lactoferrin on the innate immune response in elderly in a pilot study. Furthermore, support of this effect by GOS and Vitamin D will be studied.

Study design

The study will be designed as a parallel double-blind placebo-controlled trial, in which healthy human elderly subjects (female) will receive 3 weeks supplementation with LF only, followed by 3 weeks LF + GOS, followed by 3 weeks LF + GOS + vitamin D. A control group receiving placebo will be included to check possible confounding of results by time effects. The 9 weeks of intervention will be preceded by a 2 weeks run-in period with limited dietary prescriptions.

Blood and fecal samples will be collected before and at 4 time points before, during and after supplementation. The total study duration is 11 weeks.

Intervention

The intervention group will receive 3 weeks supplementation with LF only, followed by 3 weeks LF + GOS, followed by 3 weeks LF + GOS + vitamin D. The placebogroup will receive maltodextrin.

Study burden and risks

The risks of participation in this study are limited. Since the intervention and placebo products are regular milk ingredients and supplements, which have been used in infants, adults and elderly subjects, the risks associated with

participation in this study are considered limited.
The main burden of this study consists of the compliance to take a daily dose of the intervention product, and blood sampling and fecal sample collection at 4 timepoints.

Contacts

Public
FrieslandCampina Nederland BV

Bronland 20
Wageningen 6708 WH
NL
Scientific
FrieslandCampina Nederland BV

Bronland 20
Wageningen 6708 WH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Female
* Age 65-85 years (if sufficient candidate participants are available, subjects with a higher age (preferentially ><=75 yr) will be included)
* BMI 20-30 kg/m2
* Non-smoking
* Generally healthy as assessed by the NIZO lifestyle and health questionnaire (*Verklaring

leefgewoonten en gezondheid*).
* Regular and normal Dutch eating habits as assessed by the NIZO lifestyle and health questionnaire (3 main meals per day)
* Veins suitable for cannulation (blood sampling)
* Voluntary participation
* Having given written informed consent
* Willing to comply with study procedures
* Accept use of all encoded data, including publication, and the confidential use and storage of all data for 15 years.
* Accept disclosure of the financial benefit of participation in the study to the authorities concerned

Exclusion criteria

* Having chronic inflammatory or autoimmune diseases such as rheumatoid arthritis, type 1 diabetes, inflammatory bowel disease
* Disease of GI tract (including major gastrointestinal tract surgery such as gastrectomy, gastroenterostomy, bowel resection, known or suspected gastrointestinal disorders, colon or GI tract cancer), liver, gall bladder, kidneys, thyroid gland
* Immune-compromised
* Use of vitamin supplements containing vitamin D and not willing to discontinue this during the study
* Use of anti-inflammatory drugs (for corticosteroids and NSAIDs : frequency >1 per week)
* Use of immunosuppressive drugs
* Excessive alcohol usage (>3 consumptions/day or >15 consumptions/week)
* Participation in any clinical trial including blood sampling and/or administration of substances within 60 days before inclusion in this study
* Use of hormonal replacement therapy
* Mental status that is incompatible with the proper conduct of the study
* A self-reported milk allergy or sensitivity to dairy ingredients
* Unexplained weight loss or weight gain of > 3 kg in the 3 months prior to pre-study screening
* First and second degree relatives of personnel of NIZO food research or Wageningen University, department of Cell Biology and Immunology or Human Nutrition
* Not having a general practitioner
* Not willing to accept information-transfer concerning participation in the study, or information regarding his health, like laboratory results and eventual adverse events to and from his general practitioner
* Holiday to a sunny country during the study, starting from inclusion
* Light therapy during the study, starting from inclusion
* Use of prebiotic supplements during 2 months before study start, and during 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):	12-01-2017
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	15-08-2016
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	11-11-2016
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	07-11-2017
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL57345.081.16