Nonspecific immune function in elderly after 6 weeks intake of the Pentagon module.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27627

Source
Nationaal Trial Register

Brief title
NIPEN

Health condition

Elderly subjects (male and female)

Sponsors and support

Primary sponsor: Danone Research - Centre for Specialised Nutrition
Source(s) of monetary or material Support: Danone Research - Centre for Specialised Nutrition

Intervention

Outcome measures

Primary outcome

Ex vivo phagocytic capacity of monocytes and granulocytes in whole blood.

Secondary outcome

1. Ex vivo oxidative burst capacity of monocytes and granulocytes in whole blood;

2. NK cell activity in PBMC;

3. NK cell number in PBMC;

4. Gut microbiota composition (e.g. % of bifidobacteria, lactobacilli);

5. Faecal parameters: pH, short-chain fatty acids, lactic acid;

6. Tolerance and safety parameters: tolerance by questionnaires, adverse events, laboratory safety parameters.

Study description

Background summary

In this trial the effect of the test product will be compared to the control product on the non-specific immune function in elderly. Subjects will be using the study product twice a day for 6 weeks.

Study objective

Usage of the Pentagon Module will improve nonspecific immune function.

Study design

1. Visit 0 = screening (Day -21 max.);

2. Visit 1 = Day 1 (start of intervention);

3. Visit 2 = Day 21;

4. Visit 3 = Day 42 (end of intervention);

5. Follow Up phone call = Day 49.

Intervention

Duration of intervention: 6 weeks (total duration study maximal 10 weeks).

Test group: Twice daily intake of the test product named Pentagon module.

Control group: Twice daily intake of the control product which is an isocaloric product.

Both products are powders that need to be solved prior to intake.

After screening for eligibility weight will be measured 3 times, stool and blood samples will be taken 3 times and tolerance questionnaires will be completed during 22 days.

(Serious) adverse events will be monitored from start study until 1 week after completion of the intervention period.

Contacts

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Eligibility criteria

Inclusion criteria

1. Elderly subject (male/female) = or > 65 years of age;

2. 19.0 kg/m2 < BMI < 32.0 kg/m2;

3. Subject is willing and able to comply with the protocol, including:

A. Refrain 3 weeks prior to start study (Visit 1) and for the duration of the study from:

a. The use of probiotic supplements and food containing probiotics;

b. The use of prebiotic or fibre containing supplements;

c. The use of the n-3 fatty acids EPA and/or DHA containing supplements (e.g. fish oil);

d. The use of non-steroidal anti-inflammatory drugs (NSAIDs).

B. Maintaining dietary habits for the duration of the study;

C. Filling in a tolerance questionnaire (Day
-4-14, Day 38 - 41).

4. Non-smoking since 6 months prior to start study (Visit 1);

5. Regular bowel movement (at least 1 bowel movement in 3 days);

6. Subject has given written informed consent.

Exclusion criteria

1. Any (history of) gastrointestinal disease or surgery that interferes with current gastrointestinal function (e.g. inflammatory bowel disease, gastroparesis, gastrectomy);

2. Known allergy to milk, milk products;

3. Diabetes mellitus;

4. Any form of cancer in the last 5 years prior to Visit 1, except basal cell carcinomas;

5. Lactose intolerance (that cannot be
managed with lactase tablets /capsules /drops);

6. Strong dislike of the flavour orange;

7. Any altered immune function, such as:

A. Any allergy (e.g. hay fever, dust mite allergy);

B. Any auto-immune disease (e.g. rheumatoid arthritis);

C. Psoriasis.

8. In the last 7 days prior to Visit 1:

A. Fever;

B. Gastrointestinal symptoms such as nausea, vomiting, diarrhea;

C. Respiratory symptoms such as cough, runny or congested nose, sore throat;

9. Medication within 3 weeks prior to start study (Visit 1) or planned during study period:

A. That interferes with current gastrointestinal function (e.g. opiates. laxatives, H2 receptor antagonists, proton pump-inhibitors);

B. Anti-asthma medication;

C. Anti-allergy medication;

D. Antibiotics;

E. (Any kind of) immunosuppressive drugs including corticosteroids (oral, inhaled or topical);

F. Non-steroidal anti-inflammatory drugs, including low dose aspirin.

10. Planned hospitalization during the study period;

11. Recent (unintended) weight loss of more than 5% in the 4 weeks prior to start of study (Visit 1);

12. Requirement for any nutritional support;

13. Requirement for a fibre-free diet;

14. On a weight loss or vegetarian diet;

15. Current alcohol use of more than 21 glasses per week for males or 14 glasses per week for females or drug abuse;

16. Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements;

17. Participation in any other intervention study concomitantly or within 12 weeks of study entry (Visit 1).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-04-2009
Enrollment:	64
Type:	Actual

Ethics review

Positive opinion

Date:	04-05-2009
Application type:	First submission

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
NTR-new	NL1693
NTR-old	NTR1794
Other	Danone Research : Sip.2.C/A/2
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A