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

Gepubliceerd: 04-05-2009 Laatst bijgewerkt: 18-08-2022

Usage of the Pentagon Module will improve nonspecific immune function.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27627

Bron
Nationaal Trial Register

Verkorte titel
NIPEN

Aandoening

Elderly subjects (male and female)

Ondersteuning

Primaire sponsor: Danone Research - Centre for Specialised Nutrition
Overige ondersteuning: Danone Research - Centre for Specialised Nutrition

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

Usage of the Pentagon Module will improve nonspecific immune function.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	27-04-2009
Aantal proefpersonen:	64
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	04-05-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A