

CAMEL.

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Probiotic supplementation in young infants (1st 2 years of life) has a therapeutic effect, associated with upregulation of tolerance for cow's milk allergens, as well as combined with local and systemic immunomodulation and improvement of...

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

Samenvatting

ID

NL-OMON28739

Bron

NTR

Verkorte titel

CAMEL

Ondersteuning

Primaire sponsor: Friesland Foods

Overige ondersteuning: SENTER

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Development of tolerance for cow's milk, observed by a challenge test (double blind) after 12 months of treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

In a group of young children with early manifestation of allergic disease, namely cow's milk allergy, the course of cow's milk allergy, as well as other allergic manifestations, and the development of the immune system will be followed prospectively.

Children under the age of 6 months with cow's milk allergy will be included in this intervention study. Intervention will be performed using probiotics, double blind centrally randomised, in 50 % of the participants during a period of 12 months, which will be administered to a standard hydrolysed formula for all participants.

Doel van het onderzoek

Probiotic supplementation in young infants (1st 2 years of life) has a therapeutic effect, associated with upregulation of tolerance for cow's milk allergens, as well as combined with local and systemic immunomodulation and improvement of allergic manifestations in the gut, skin and airways.

Onderzoeksproduct en/of interventie

In children with cow's milk allergy diagnosed by an elimination-challenge test (open), the longitudinal development will be followed from inclusion (< age 6 months) during 18 months.

All participants will receive a hydrolysed formula (caseïne hydrolysate, Allergycare®, Friesland Foods).

2 probiotic strains (one lactobacillus and one bifidobacteria) will be added to the Allergycare® in 50% of the participants, as intervention for 12 months, randomised, double-blind.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Under 6 months of age;
2. Documented cow's milk allergy, judged by an elimination-challenge test (open) and re-elimination, in conformity with the guidelines of ESPGHAN (European Society for Pediatric Gastroenterology, Hepatology and Nutrition);
3. Informed consent by the parents/care-takers.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Breast-feeding during the study;
2. Age > 6 months;
3. Chronic diseases, which may be relevant for this study, such as pre-existing chest abnormalities (e.g. BPD and relevant congenital abnormalities), gastro-intestinal diseases (celiac disease, enzyme disorders) and metabolic diseases;
4. Prematurity; < 32 weeks;
5. Congenital abnormalities, which may be relevant for this study;
6. Use of systemic drugs for allergy (corticosteroids and antihistamines).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-01-2003
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	12-09-2005
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	NL301
NTR-old	NTR339

Register

Ander register
ISRCTN

ID

: N/A
ISRCTN04799749

Resultaten

Samenvatting resultaten

N/A