CAMEL.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28739

Source
NTR

Brief title
CAMEL

Sponsors and support

Primary sponsor: Friesland Foods
Source(s) of monetary or material Support: SENTER

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. The severity of cow milk allergy related features, namely variables onf physical inspection, as well as observed features by the parents in a questionnaire/diary;

2. Assessment of skin features will be performed by the objective SCORAD, as a measure for the severity of atopic dermatitis;

3. Need for medication;

4. Quality of life, as judged by the parents and noted in a questionnaire/diary;

5. Weight and height;

6. Effects on immuno(dys)regulation; on sensibilisation, namely allergen-specific IgE and epitope-specific IgE, T-lymfocyte subsets, as measured by membrane markers, signal-transduction proteins related to immunomodulation, In-vitro allergen–stimulated T-lymphocyte activity with specific cytokine detection.

Study description

Background summary

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.

Study objective

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.

Intervention

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 recieve 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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2003
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-09-2005
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	NL301
NTR-old	NTR339
Other	: N/A
ISRCTN	ISRCTN04799749

Study results

Summary results
N/A