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CAMEL: Cow's milk Allergy Mediated by Elimination and Lactobacilli

Submission date	Recruitment status
20/12/2005	No longer recruiting
Registration date	**Overall study status**
20/12/2005	Completed
Last Edited	**Condition category**
14/06/2019	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR339

Study information

Scientific Title
CAMEL: Cow's milk Allergy Mediated by Elimination and Lactobacilli

Acronym
CAMEL

Study objectives
Probiotic supplementation in young infants (first 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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Multicentre, randomised, double blind, placebo controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Allergy to cow's milk

Interventions
In children with cow's milk allergy diagnosed by an elimination-challenge test (open), the longitudinal development will be followed from inclusion (less than age 6 months) during 18 months. All participants will receive a hydrolysed formula (caseïne hydrolysate, Allergycare®, Friesland Foods). Two 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.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Probiotic strains (lactobacillus, bifidobacteria), Allergycare®

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

Secondary outcome measures
1. The severity of cow milk allergy related features, namely variables on 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 allergenstimulated T-lymphocyte activity with specific cytokine detection

Overall study start date
01/01/2003

Completion date
01/01/2008

Eligibility

Key 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

Participant type(s)
Patient

Age group
Child

Upper age limit
6 Months

Sex
Both

Target number of participants
200

Total final enrolment
119

Key exclusion criteria
1. Breast-feeding during the study
2. Aged greater than 6 months
3. Chronic diseases, which may be relevant for this study, such as pre-existing chest abnormalities (e.g. broncho-pulmonary dysplasia [BPD] and relevant congenital abnormalities), gastro-intestinal diseases (celiac disease, enzyme disorders) and metabolic diseases
4. Prematurity less than 32 weeks
5. Congenital abnormalities, which may be relevant for this study
6. Use of systemic drugs for allergy (corticosteroids and antihistamines)

Date of first enrolment
01/01/2003

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
3015 GJ

Sponsor information

Organisation
Friesland Foods (Netherlands)

Sponsor details

Blankenstein 142
Meppel
Netherlands
7943 PE

Sponsor type
Industry

Website
http://www.nl.frieslandcampina.com/

ROR
https://ror.org/025mtxh67

Funder(s)

Funder type
Government

Funder Name
SENTER - A branch of the Dutch Ministry of Economic Affairs (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2008	14/06/2019	Yes	No