

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

Submission date
20/12/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
20/12/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
14/06/2019

Condition category
Injury, Occupational Diseases, Poisoning

☐ 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

Protocol serial number
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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Child

Upper age limit

6 months

Sex

All

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)

ROR

<https://ror.org/025mtxh67>

Funder(s)

Funder type

Government

Funder Name

SENER - A branch of the Dutch Ministry of Economic Affairs (The Netherlands)

Results and Publications

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