Hypoallergenicity of an extensively hydrolyzed whey protein infant formula in children with cow's milk allergy.

No registrations found.

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

Summary

ID

NL-OMON25061

Source
Nationaal Trial Register

Brief title
CMA

Health condition

Cow's milk allergy (CMA).

Sponsors and support

Primary sponsor: Danone Research - Centre for Specialised Nutrition
Source(s) of monetary or material Support: Danone Research - Centre for Specialised Nutrition

Intervention

Outcome measures

Primary outcome

Phase A: immediate and delayed allergic reactions to DBPCFC with the extensively hydrolyzed whey protein-based infant formula;

Phase B: gastro-intestinal tolerability and allergic symptoms.

Secondary outcome

Phase A: none;
Phase B: product convenience.

Study description

Background summary

Cow’s milk allergy is caused by an abnormal reaction of a child’s immune system to milk proteins and is characterized by rapid appearance of symptoms, such as wheezing, vomiting, diarrhea, abdominal pain, and exacerbation of eczema, after consumption of cow’s milk proteins.

Treatment of cow’s milk allergy in children therefore means total avoidance of cow’s milk and use of special developed so−called ‘hypoallergenic’ milk formulas. In the ‘hypoallergenic' milk formulas the milk proteins are broken down into small pieces, so the immune system does not recognize the proteins as dangerous anymore and no allergic reaction is provoked.

Even hypoallergenic formulas might contain some cow’s milk proteins that were not broken down sufficiently. The remaining bigger proteins might still provoke allergic reactions in children with cow’s milk allergy. Therefore hypoallergenic formulas first need to be tested in research studies before they can be generally used to treat children with cow’s milk allergy. Such studies must demonstrate that the formula is tolerated by a substantial percentage of children with cow’s milk allergy and does not cause allergic responses.

In the current study a new hypoallergenic milk formula will be tested in children aged 0 to 24 months with cow's milk allergy. For the participants, the study will last a minimum of 6 weeks and consists of several hospital visits and assessments, including a double−blind, placebo−controlled food challenge. Furthermore, the participant's parents should complete diaries regarding their child's food intake (including study product) and gastro−intestinal/allergic symptoms.

Study objective

The formula will be tolerated by at least 90% of the children with cow's milk allergy with a

confidence interval of 95%.

Study design

Screening will take at least one hospital visit. As from the start of phase A, the study will take 3 hospital visits and 3 phone calls.

Intervention

Duration of intervention:
Phase A: one day, twice;
Phase B: two weeks.

Intervention group: extensively hydrolyzed whey protein based infant formula.

Control group: amio acid-based infant formula.

Contacts

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Eligibility criteria

Inclusion criteria

1. Children with cow's milk allergy, diagnosed by a double-blind, placebo-controlled food challenge (DBPCFC) within 4 weeks prior to study start;

2. Aged from birth to 24 months;

3. Expected daily intake of at least 500ml of the study product during phase B;

4. Written informed consent of both parents/caretakers.

Exclusion criteria

1. Children consuming mother's milk at the time of inclusion and during the trial;

2. Intolerance for lactose or any other component of the study product(s);

3. History of anaphylactic reaction, including severe cardiovascular symptoms (shock), severe laryngeal edema, and bronchus obstruction;

4. History of cardiovascular, gastrointestinal, hepatic, renal or respiratory chronic disease other than allergy;

5. Major congenital abnormalities;

6. Inability to adhere to protocol. instructions.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	20-02-2009
Enrollment:	47
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-02-2009
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	NL1575
NTR-old	NTR1654
Other	: CMA.1.C/A/0
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A