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

Gepubliceerd: 02-02-2009 Laatst bijgewerkt: 18-08-2022

The formula will be tolerated by at least 90% of the children with cow's milk allergy with a confidence interval of 95%.

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

Samenvatting

ID

NL-OMON25061

Bron
Nationaal Trial Register

Verkorte titel
CMA

Aandoening

Cow's milk allergy (CMA).

Ondersteuning

Primaire sponsor: Danone Research - Centre for Specialised Nutrition
Overige ondersteuning: Danone Research - Centre for Specialised Nutrition

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

The formula will be tolerated by at least 90% of the children with cow's milk allergy with a confidence interval of 95%.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	20-02-2009
Aantal proefpersonen:	47

Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

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

Resultaten

Samenvatting resultaten
N/A