A prospective double blind randomised controlled study to evaluate the immunological benefits and clinical effects of an elimination diet using an amino acid formula (AAF) with an added pre-probiotic blend in infants with Cow's Milk Allergy (CMA).

Gepubliceerd: 28-11-2012 Laatst bijgewerkt: 18-08-2022

Development of oral tolerance to cow's milk at 12 months of treatment in infants with IgE mediated Cow's Milk Allergy (CMA) on control or test formula.

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28608

Bron
NTR

Verkorte titel
PRESTO

Aandoening

Infants with Cow's Milk Allergy

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary study endpoint is the proportion of the infants who develop oral tolerance to cow’s milk.

Toelichting onderzoek

Achtergrond van het onderzoek

This study is initiated to evaluate the immunological benefits and clinical effects of an elimination diet using an amino acid formula with an added pre-probiotic blend in infants with Cow’s Milk Allergy.

The parents/guardians of infants with a (likely) diagnosis of IgE-mediated CMA will be provided with information about the study by the investigating centre and invited to take part. At Screening, data on the subject’s characteristics, medical history, medications used and feeding history will be collected. Clinical assessment to rate allergy symptoms will be performed.
The parents/guardian will be provided with and advised on the use of the study product. Parents/guardians of subjects will be asked about acceptance and tolerance of formula. Subjects will take the study product for 12 months with visits to the clinic at 6 and 12 months. At these clinic visits, a clinical assessment and rating of allergic symptoms will be recorded. At completion of the 12 month intervention, subjects will transfer to an age appropriate formula and be followed-up at 24 and 36 months. At these clinic visits, a clinical assessment, rating of allergic symptoms and incidence of other non-food allergy symptoms during the past year will be recorded.

Doel van het onderzoek

Development of oral tolerance to cow's milk at 12 months of treatment in infants with IgE mediated Cow's Milk Allergy (CMA) on control or test formula.

Onderzoeksopzet

1. Screening;

2. Randomisation;

3. 6 months;

4. 1 yr and 2 yr after randomisation.

Onderzoeksproduct en/of interventie

Duration of intervention: 12 months.

Intervention group: AAF with prebiotics and probiotics (synbiotics) formulation.

Control group: AAF without synbiotics.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Infants < 13 months of age i.e. up to and including the day before the infant is 13 months of age;

2. Infants with a clinical history of reaction and sensitised to cow's milk by either blood CM specific IgE>0.1kU/L and/or Skin Prick Testing (SPT) wheal size >= 3mm before entering the

study. The diagnosis of IgE mediated CMA should be confirmed by cow's milk challenge or history of an anaphylaxis reaction;

3. Infants expected to consume the required amount of formula during the study intervention.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Infants in non-Asian countries less than 2500 g at birth. Infants in Asian countries less than 2250 g at birth;

2. Infants less than 37 weeks gestation and requires specific premature formula at the time of study entry;

3. Infants with severe concurrent illness;

4. Use of anti- histamines in the 4 days preceding study entry;

5. Use of systemic corticosteroids in the 4 weeks preceding study entry and not willing to exclude corticosteroids in the 4 weeks preceding each study visit;

6. Use of probiotic bacteria or probiotic containing drinks/supplements;

7. Use of systemic antibiotics or anti-mycotic drugs 4 weeks preceding study entry;

8. Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements;

9. Participation in any other studies involving investigational or marketed products concomitantly or within two weeks prior to entry into the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2013
Aantal proefpersonen:	170
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL3567
NTR-old	NTR3725
Ander register	Nutricia Research : NEO.1.C.E
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A