

Partial hydrolyzed protein in cows milk protein allergy risk reduction.

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There will be no significant difference in prevalence of allergy in infants with increased risk for CMA when fed with partially hydrolysed whey protein or extensively hydrolysed casein formula, at the age of 6 months.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24148

Bron

NTR

Verkorte titel

NPAIR

Aandoening

Cow's milk allergy, infants with CMA risk

Ondersteuning

Primaire sponsor: Laboratorios PiSa, Mexico
IMSS Pachuca, Hidalgo, Mexico

Overige ondersteuning: FrieslandCampina

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Prevalence of cow's milk allergy, recorded on three-day diary allergy symptom, and

confirmed by double blind challenge test;

2. Tolerance of the formula by three-day questionnaire and crying diaries on each time point;

3. Antropometric measurements: Weight, length and head circumference, on each time point.

Toelichting onderzoek

Achtergrond van het onderzoek

The best protection, or the best preventive allergy strategy, starts with the prevention of early sensitization of the consumer to give the intestine and immune system time to mature. Maturation of the non-sensitized immune system creates normal oral tolerance instead of tolerance based on counterbalancing the hyper response.

The aim of the study is to confirm that partialy hydrolysed protein does not sensitize the immune system, similarly to the effects found in the extensively hydrolysed protein formula. The study will be performed in full term mexican infants.

Doel van het onderzoek

There will be no significant difference in prevalence of allergy in infants with increased risk for CMA when fed with partially hydrolysed whey protein or extensively hydrolysed casein formula, at the age of 6 months.

Onderzoeksopzet

T= 1 week;

T= 1 mo;

T= 2 mo;

T= 3 mo;

T= 6 mo.

Onderzoeksproduct en/of interventie

Friso Preventive HA (Intervention):

The primary characteristic of Friso Preventive HA is an infant formula based on partially hydrolysed whey protein. It is a product primary designed for infants with a high risk to develop cow milk allergy (CMA) because it contains medium-fragment proteins. 50% of the proteins have a molecular weight lower than 1500 dalton.

Friso Allergy care (Control):

Friso Allergy care infant formula is based on extensively hydrolysed casein protein. It is especially developed for infants with CMA diagnostic. 97% of the proteins have a molecular weight lower than 1500 dalton.

The duration of the intervention will be for 6 months.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Increased risk for allergy (mother, father, brother or sister with an allergic disease);
2. Full term newborn.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. Severe acquired or congenital diseases;
2. Gestational age of less than 37 weeks;
3. Birth weight of less than 2500 grams;
4. Intake of any formulae with intact protein during the first week of life;
5. Breast feeding more than two weeks;
6. Symptoms of cow milk allergy at the time of inclusion: eczema, rashes;
7. Abnormalities in heart, liver, kidneys, or central nervous system;
8. Supplementary feeding during the first four months of life;
9. Use of medication over a longer period of time, which affects the outcome of the study;
10. Use of cream that contains casein or other milk proteins;
11. Incapability of the parents to comply with the study protocol.

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2011
Aantal proefpersonen:	200

Type:

Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:

26-07-2011

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	NL2861
NTR-old	NTR3003
Ander register	FrieslandCampina : Nutr-MC-001-2011
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A