

# Partial hydrolyzed protein in cows milk protein allergy risk reduction.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON24148

### Source

Nationaal Trial Register

### Brief title

NPAIR

### Health condition

Cow's milk allergy, infants with CMA risk

## Sponsors and support

**Primary sponsor:** Laboratorios PiSa, Mexico

IMSS Pachuca, Hidalgo, Mexico

**Source(s) of monetary or material Support:** FrieslandCampina

## Intervention

## Outcome measures

### Primary outcome

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.

### **Secondary outcome**

The moment of onset of cow's milk protein allergy during the intervention period for both of the formulae.

## **Study description**

### **Background summary**

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.

### **Study objective**

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.

### **Study design**

T= 1 week;

T= 1 mo;

T= 2 mo;

T= 3 mo;

T= 6 mo.

### **Intervention**

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.

## Contacts

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## Eligibility criteria

### **Inclusion criteria**

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

## Exclusion criteria

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.

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2011
Enrollment:	200

Type: Anticipated

## Ethics review

Positive opinion

Date: 26-07-2011

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

## Study results

### Summary results

N/A