

# 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).

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON28608

### Source

NTR

### Brief title

PRESTO

### Health condition

Infants with Cow's Milk Allergy

## 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

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

#### Secondary outcome

1. Maturation of the GI (immune) system in cow's milk allergic infants;
2. Effectiveness of the study product in the dietary management of CMA/food allergy;
3. Frequency of other allergies (non-food).

## Study description

#### Background summary

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.

#### Study objective

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.

## Study design

1. Screening;
2. Randomisation;
3. 6 months;
4. 1 yr and 2 yr after randomisation.

## Intervention

Duration of intervention: 12 months.

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

Control group: AAF without synbiotics.

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

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 > 0.1 kU/L and/or Skin Prick Testing (SPT) wheal size  $\geq$  3 mm 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.

## Exclusion criteria

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.

## Study design

### Design

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

Control: Active

## Recruitment

NL  
Recruitment status: Recruitment stopped  
Start date (anticipated): 01-01-2013  
Enrollment: 170  
Type: Actual

## Ethics review

Not applicable  
Application type: Not applicable

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

## Study results

## Summary results

N/A