A study of hypoallergenic bottle feeding for infants with suspected cow's milk allergy

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20308

Source
Nationaal Trial Register

Brief title
SInFoNIA

Health condition

Non-IgE mediated cow's milk allergy
Niet-Ige gemedieerde koemelkallergie

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: Nutricia Research
Health Holland (TKI)

Intervention

Outcome measures

Primary outcome

- Time to symptom resolution

- Grade of symptom resolution

Secondary outcome

- Time point of acquired tolerance to cow's milk

- Characteristics of children needed to switch from eHF to AAF

- Explorative: immunology markers, microbiome analysis

Study description

Background summary

The guidelines used for the diagnosis and management of cow’s milk allergy (CMA) are largely based on research in children with the classical phenotype of IgE-mediated allergic disease. These guidelines do not focus on non-IgE mediated CMA. In fact they may even be ineffective for this group. In IgE-mediated CMA, extensively hydrolysed formula (eHF) is considered an effective standard therapy for the majority of patients, with amino acid formula (AAF) being reserved for associated failure to thrive or insufficient treatment with eHF. However, in non-IgE mediated CMA, literature and expert opinion suggest that this formula frequently fails to resolve the symptoms. AAF may be indicated in a large proportion of non-IgE mediated CMA. Currently, the pathophysiology of non-IgE mediated CMA and, as a result, the most suitable formula for these patients is not known. Preliminary data suggest that AAF has anti-inflammatory effects on the gastrointestinal tract and therefore could do better in comparison with eHF. The aim of this study is to compare the clinical outcomes of early introduction of eHF versus AAF in non-IgE mediated CMA.

Study objective

Early introduction of an amino-acid based formula (AAF; Neocate® Syneo) in infants with non-IgE mediated cow's milk allergy (CMA) accelerates resolution of clinical symptoms compared to a whey based extensively hydrolyzed formula (eHF; Nutrilon Pepti).

Study design

- V1: Day 0

- V2: Day 28

- V3: Day 56

- V4/5: Day 35 and 42 or Day 91 and 98

- FU: 6 months, 1 year

Intervention

Treatment with an extensively hydrolyzed whey based formula (eHF; Nutrilon Pepti) is compared to treatment with an amino acid-based formula (AAF; Neocate® Syneo).

Contacts

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Eligibility criteria

Inclusion criteria

- Infants ≤12 months of age.

- Suspected non-IgE mediated CMA¡¯ as defined by a symptom score of at least 15 points and the pediatrician¡¯s opinion of a possible benefit from an elimination diet.

- Symptoms are suspected to be related to cow's milk ingestion and not explained otherwise.

Exclusion criteria

- Infants born <37 weeks gestation who require specific premature formula at time of study entry.

- Infants less than 2500 g at birth.

- Use of any hypoallergenic formulas (partially hydrolysed formula, eHF and/or AAF), <4 weeks prior to the first study visit, more than 1 bottle per week.

- An alternative diagnosis that is more probable than non-IgE mediated CMA (as decided by the expert team).

- Evidence of ¡°severe concurrent illness¡± (as specified in protocol).

- The use of medication (as further specified in protocol) <4 weeks prior to the first study visit.

- Clinical history of allergy, hypersensitivity or intolerance to the excipients of the study formulas.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2018
Enrollment:	168
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 48638
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7164
NTR-old	NTR7387
CCMO	NL65543.041.18
OMON	NL-OMON48638

Study results