An Amino Acid based Formula with synbiotics: Effects on gut microbiota diversity and clinical effectiveness in suspected gastrointestinal non-IgE mediated Cow’s Milk Allergy (ASSIGN I).

Gepubliceerd: 01-05-2013 Laatst bijgewerkt: 13-12-2022

To assess the effect of an Amino Acid based Formula (AAF) with synbiotics on the balance of major constituents of the gut microbiota, specifically Bifidobacteria vs. Clostridial groups.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20641

Bron
Nationaal Trial Register

Verkorte titel
ASSIGN I

Aandoening

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

Counts of Bifidobacteria and counts of Eubacterium rectale/ Clostridium coccoides at week 0 and week 8 (fluorescence in situ hybridization (FISH).

Toelichting onderzoek

Achtergrond van het onderzoek

This study is initiated to evaluate the effect of an Amino Acid based Formula with pre-probiotics on the gut microbiota and clinical effectiveness on allergic symptoms in infants with suspected non-IgE Cow's Milk Allergy.
The parents/guardians of infants with a clinical history of a reaction or a suspected non-IgE mediated allergy to cow's milk protein will be provided with information about the study by the investigating centre and invited to take part.
The subjects will be screened for in- and exclusion criteria at the screening visit (V1). During the screening visit, data on the medical history, subject's characteristics, medications used and feeding history will be collected.
At the baseline visit (V2) clinical assessments of allergic symptoms (SCORAD for skin symptoms and 24hr recall) using clinician rating scales will be carried out. Anthropometrics will be measured and a saliva sample and stool sample will be collected. If the stool sample collection is not possible during the visit, a stool sampling kit and instructions will be given to collect the stool sample at home. For the stool sample collection during the week 8, the stool sampling kit will be given to the parents at V2 to collect the stool sample at home.
The parents/guardians will be provided with study product and a parent diary and advised on use of the study product and on completion of the parent diary in weeks 1, 4 and 8. Parents/guardians of subjects will be asked about acceptance and tolerance of formula. Subjects will take their study product for a total of eight weeks with a final visit (V3) at week 8. At this visit clinical assessment of allergic symptoms completed in the parent diary will be carried out to review any issues. SCORAD will be performed, anthropometric measurements will be repeated and parent diaries and the frozen stool sample(s) will be provided by parents/guardians to the centre. A saliva sample will be collected during V3.
At completion of the 8 weeks, subjects will transfer to an age and condition appropriate formula following standard practice (e.g. eHF, HF, milk containing products, etc.) and will be followed up at 12 weeks (V4) and 26 weeks (V5). In case continuation on an AAF would be condition appropriate, the subjects should continue on the allocated study product until 26 weeks.
At V4 and V5, a clinical assessment of allergic symptoms completed in the parent diary will be carried out to review any issues. SCORAD for skin symptoms will be performed, anthropometric measurements will be repeated and information on formula use and introduction of any milk products will be collected by the investigator. Parent diaries and frozen stool sample(s) collected in the week before the visit will be provided by

parents/guardians to the centre.

Doel van het onderzoek

To assess the effect of an Amino Acid based Formula (AAF) with synbiotics on the balance of major constituents of the gut microbiota, specifically Bifidobacteria vs. Clostridial groups.

Onderzoeksopzet

1. Screening;
2. Randomisation;
3. Week 8;
4. week 12 – follow up;
5. week 26 – follow up.

Onderzoeksproduct en/of interventie

Duration of intervention: 8 weeks + 18 weeks follow;
Intervention group: AAF with prebiotics and probiotics (synbiotics) formulation;
Control group: AAF without synbiotics.

Contactpersonen

Publiek

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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. Clinical history or strong suspicion of an allergic reaction to cow's milk protein AND WITH at least one of the following (gastrointestinal) symptoms present at study entry:
A. Chronic pPoor weight gain AFTER the dietary inclusion of cow's milk protein;
B. Frequent (daily) regurgitation or vomiting whereby symptoms are RELATED to the cow's milk protein and not merely functional vomiting;
C. Extended periods of diarrhoea with a negative stool examination (laboratory tests negative);
D. Soft stool constipation (with/without perianal rash NOT due to infection);
E. Blood in stool;
F. Iron deficiency anaemia due to occult or macroscopic blood loss in stools NOT due to infection or dietary insufficiency;
G. Endoscopically confirmed eosinophilic enteropathy;
H. Persistent distress or colic (> 3 hours per day at least 3 days a week over 3 week period).
3. If results of a Specific IgE test (RAST) for cow's milk protein AND/OR prick test for cow's milk are available (for test(s) previously performed), these are negative or without detectable serum IgE (<0.1 kU/L);
4. Expected minimum product intake (per day) at the end of week 2 of:
A. Birth up to 6 months: 500ml;
B. From 6 months to 8 months: 450ml;
C. From 9 months onwards: 350ml;
5. Written informed consent provided by parents/ guardians, according to local law.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Infants less than 2500 g at birth;
2. Infants less than 37 weeks gestation who require specific premature formula at the time of study entry;
3. Infants with severe concurrent illness;
4. Infants with functional gastrointestinal symptoms where atopy and food allergy is NOT suspected;
5. Infants with immune autoimmune or gluten sensitive enteropathy;
6. Infants with Food Protein-Induced Enterocolitis Syndrome (FPIES);
7. Infants who have acute or chronic diarrhea secondary to confirmed infectious gastroenteritis (laboratory tests positive);
8. Behavioural disorders with food aversion or food phobia;

9. Infants who have undergone gastrointestinal surgery such as bowel resection or stoma placement;
10. Infants with Down syndrome or other syndromes where functional gastrointestinal disorders are common;
11. Use of probiotic bacteria or probiotic containing drinks/supplements in the 4 weeks preceding study entry and during the study;
12. Use of systemic antibiotics or anti-mycotic drugs 4 weeks preceding study entry and during the study;
13. Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements;
14. 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:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	20-05-2013
Aantal proefpersonen:	68
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	01-05-2013

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	NL3813
NTR-old	NTR3979
Ander register	- : NEO.1.C.F
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A