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).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20641

Source
NTR

Brief title
ASSIGN I

Health condition

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

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

Secondary outcome

To assess the effects of an AAF with synbiotics compared to an AAF without synbiotics with respect to:
1. Stool characteristics in terms of colour, frequency and consistency at week 0, 1, 4 and 8;
2. Parameters of gut health and immune status:(Faecal secretory IgA and concentrations of Short Chain Fatty Acids (SCFA); butyrate, propionate and acetate) at week 0 and 8.
A. Faecal secretory IgA;
B. Faecal concentrations of Short Chain Fatty Acids (SCFA); butyrate, propionate and acetate.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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

Contacts

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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. 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.

Exclusion criteria

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.

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):	20-05-2013
Enrollment:	68
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	01-05-2013
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	NL3813
NTR-old	NTR3979
Other	- : NEO.1.C.F
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A