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Tolerance and safety study of a new paediatric peptide feed

Submission date	Recruitment status	[ ] Prospectively registered
27/01/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/01/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/07/2009	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR451; 100027

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Multicentre, randomised, single blind, active controlled, crossover trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Paediatric peptide feed

Interventions
After baseline measurements, patients receive either their current feed (= control) for 4 weeks followed by 4 weeks paediatric peptide feed, or paediatric peptide feed for 4 weeks followed by 4 weeks on the control feed. After 4 weeks and after 8 weeks, children return to the clinic where the outcome measures are assessed. Children are invited to participate in a 3-month open extension of the study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Total score on questionnaire on gastro-intestinal tolerance: diarrhoea, constipation, nausea, vomiting, abdominal distention, flatulence and burping of paediatric peptide feed versus control feeds.

Key secondary outcome(s))
1. Stool output (frequency, volume and consistency) of paediatric peptide feed versus control feeds
2. Mean change in weight (kg) of paediatric peptide feed versus control feeds
3. Mean change in growth, expressed as z-scores for weight and height (head circumference for children younger than two years old) of paediatric peptide feed versus control feeds
4. Mean change in triceps skin fold thickness and mid arm circumference of paediatric peptide feed versus control feeds
5. Blood concentrations of serum albumin, haemoglobin, haematocrit and C-reactive protein (CRP) of paediatric peptide feed versus control feeds
6. Convenience/ease of use of paediatric peptide feed versus control feeds
7. Dietary intake of paediatric peptide feed versus control feeds

Completion date
01/10/2006

Eligibility

Key inclusion criteria
1. Children requiring a paediatric peptide feed. Some conditions where this is required may include inflammatory bowel disease, short bowel syndrome, pancreas/liver disease, chronic diarrhoea, cystic fibrosis, undiagnosed gut problems, coeliac disease.
2. Approximately 8 - 30 kg in weight
3. Peptide based feed prescribed for at least 50% of daily energy requirements
4. Expected need of peptide based feed for a minimum of 2 months
5. Written parental informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
1. Infants under 1 year of age
2. Children receiving parenteral nutrition for more than 50% energy requirements
3. Children with galactosaemia
4. Children with cow milk allergy
5. Children with medical or dietary contraindication
6. If the investigator is, for any reason, uncertain about the willingness to comply with the protocol requirements, the subject can be excluded
7. Participation in any other studies involving investigational or marketed products concomitantly or within two weeks prior to entry into the study
8. Multiple allergies

Date of first enrolment
01/10/2005

Date of final enrolment
01/10/2006

Locations

Countries of recruitment
Netherlands

Study participating centre

Numico Research B.V.
Wageningen
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6700 CA

Sponsor information

Organisation
Numico Research B.V. (Netherlands)

ROR
https://ror.org/00aj77a24

Funder(s)

Funder type
Industry

Funder Name
Numico Research B.V. (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration