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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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet

## 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 measure
Total score on questionnaire on gastro-intestinal tolerance: diarrhoea, constipation, nausea, vomiting, abdominal distention, flatulence and burping of paediatric peptide feed versus control feeds.

## Secondary outcome measures

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

### Overall study start date
01/10/2005

### 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

### Age group
Child

### Sex
Both

### Target number of participants
24

### 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
Netherlands
6700 CA

## Sponsor information

### Organisation
Numico Research B.V. (Netherlands)

### Sponsor details
P.O. Box 7005
Wageningen
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### Sponsor type
Industry

### ROR
https://ror.org/00aj77a24

## Funder(s)

### Funder type
Industry

**Funder Name**
Numico Research B.V. (Netherlands)

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration