

Tolerance and safety study of a new paediatric peptide feed.

No registrations found.

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

Summary

ID

NL-OMON25485

Source

NTR

Brief title

N/A

Health condition

Children requiring a paediatric peptide feed for at least 8 weeks. This can be due to causes such as inflammatory bowel disease, short bowel syndrome, pancreas/liver disease, chronic diarrhoea, cystic fibrosis, undiagnosed gut problems, coeliac disease.

Sponsors and support

Primary sponsor: Numico Research B.V.

Source(s) of monetary or material Support: Numico

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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, hemoglobin, 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.

Study description

Background summary

N/A

Study objective

N/A

Study design

N/A

Intervention

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 an 3-month open extension of the study.

Contacts

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Eligibility criteria

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.

Exclusion criteria

1. Unsuitable for 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.

Study design

Design

| | |
|---------------------|-------------------------------|
| Study type: | Interventional |
| Intervention model: | Crossover |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |

Recruitment

| | |
|---------------------------|---------------------|
| NL | |
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-10-2005 |
| Enrollment: | 24 |
| Type: | Actual |

Ethics review

| | |
|-------------------|------------------|
| Positive opinion | |
| Date: | 07-10-2005 |
| 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 | NL411 |
| NTR-old | NTR451 |
| Other | : 100027 |
| ISRCTN | ISRCTN48462333 |

Study results

Summary results

N/A