Tolerance and safety study of a new paediatric peptide feed.

Gepubliceerd: 07-10-2005 Laatst bijgewerkt: 18-08-2022

N/A

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

Samenvatting

ID

NL-OMON25485

Bron
NTR

Verkorte titel
N/A

Aandoening

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.

Ondersteuning

Primaire sponsor: Numico Research B.V.
Overige ondersteuning: Numico

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

control feeds.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

N/A

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2005
Aantal proefpersonen:	24
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	07-10-2005
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	NL411
NTR-old	NTR451
Ander register	: 100027
ISRCTN	ISRCTN48462333

Resultaten

Samenvatting resultaten
N/A