Effect of a fibre-enriched versus standard pediatric tube feed on the intestinal flora, gastrointestinal function and nutritional status of 7-12 year old children.

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Improvement of the intestinal microflora of children consuming a fibre-enriched versus a standard paediatric tube feed.

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

Samenvatting

ID

NL-OMON22400

Bron
Nationaal Trial Register

Verkorte titel
Tentrini Study.

Aandoening

1. Tube fed;

2. children aged 7-12 years;

3. cerebral palsy.

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Gut microflora.

Toelichting onderzoek

Achtergrond van het onderzoek

At 0, 3, 4 and 7 months, subjects visited the clinic for anthropometric and body composition measurements, blood parameters and stool microflora analysis. 48 hr dietary recall was performed preceding each visit. Stool characteristics and gastrointestinal discomfort were reported.

Doel van het onderzoek

Improvement of the intestinal microflora of children consuming a fibre-enriched versus a standard paediatric tube feed.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Duration intervention: 7 Months.

Two paediatric tube feeds:

1. Fibre-enriched;

2. Standard (fibre-free).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Children:

1. male and female subjects, aged 7-12 years, who are expected to need tube feeding for at least 8 months;

2. >12 years of age, but with an age-weight status comparable to 7-12 years (21-45kg) are eligible;

3. currently tube fed with a fibre-free formula for the last 2 (or more) weeks;

4. for whom tube feeding contributes to at least 50% of total energy intake;

5. who are stable with respect to their disease/pathological condition;

6. whose daily nutritional intake is stable during the study period;

7. written parental informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Children:

1. with Cow’s Milk Allergy, inflammatory bowel disease or bowel resection;

2. requiring a fibre-free diet;

3. on antibiotic therapy during the 2 weeks preceding the study;

4. using laxative therapy other than polyethylene glycol or paraffin oil during the 2 weeks preceding the study;

5. with acute diarrhoea during the 2 weeks preceding the study;

6. consuming more than 1 serving of yoghurt or fermented dairy product during the 2 weeks preceding the study;

7. receiving supplementation with Fe and/or any of the other monitored micronutrients during the month prior to inclusion;

8. with disease associated gastro-intestinal disorders (short-bowel disease, malabsorption, cystic fibrosis);

9. with known dislipoprotidemia;

10. participating simultaneously in another clinical trial.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2003
Aantal proefpersonen:	27
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	23-06-2006
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	NL706
NTR-old	NTR716
Ander register	: Project Number 100013.
ISRCTN	Incomplete info for ISRCTN

Resultaten

Samenvatting resultaten

N/A