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.

No registrations found.

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

Summary

ID

NL-OMON22400

Source
Nationaal Trial Register

Brief title
Tentrini Study.

Health condition

1. Tube fed;

2. children aged 7-12 years;

3. cerebral palsy.

Sponsors and support

Primary sponsor: Numico Research B.V.
Source(s) of monetary or material Support: Numico Research B.V.

Intervention

Outcome measures

Primary outcome

Gut microflora.

Secondary outcome

1. Bowel function: stool frequency, consistency and reduction of laxative use;

2. Gastro-intestinal intolerance (eg: bloating, abdominal pain, nausea);

3. Nutritional status, assessed by measuring anthropometrics, micronutrient status and body composition.

Study description

Background summary

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.

Study objective

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

Study design

N/A

Intervention

Duration intervention: 7 Months.

Two paediatric tube feeds:

1. Fibre-enriched;

2. Standard (fibre-free).

Contacts

Public
Numico Research B.V.,
PO Box 7005
Jane McKenzie
Wageningen 6700 CA
The Netherlands
+31 (0)317 467800
Scientific
Numico Research B.V.,
PO Box 7005
Jane McKenzie
Wageningen 6700 CA
The Netherlands
+31 (0)317 467800

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2003
Enrollment:	27
Type:	Actual

Ethics review

Positive opinion Date:	23-06-2006
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	NL706
NTR-old	NTR716
Other	: Project Number 100013.
ISRCTN	Incomplete info for ISRCTN

Study results

Summary results
N/A