Acropolis study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19872

Source
Nationaal Trial Register

Brief title
Acropolis study

Health condition

Indication for tube nutrition

Sponsors and support

Primary sponsor: Danone Research
Source(s) of monetary or material Support: Danone Research

Intervention

Outcome measures

Primary outcome

Gastrointestinal tolerance measured by defecation pattern and self-reported GI symptoms.

Secondary outcome

N/A

Study description

Background summary

The purpose of this study is to investigate the gastrointestinal tolerance of two enteral nutrition formulae in patients receiving long term tube nutrition

Study objective

Comparison of the gastrointestinal tolerance of two enteral nutrition formulae

Study design

Defecation pattern will be monitored daily throughout the study period. Self-reported GI symptoms will be assessed at baseline, end of the first intervention period (first study product) and end of the second intervention period (second study product).

Intervention

Daily intake of study product.

Total duration of intervention: 4 weeks; 2 weeks first study product followed by 2 weeks second study product.

Specification of intervention:
The study product will replace the tube nutrition that is received by the subject prior to the trial. The tube feeding regimen is similar to pre study feeding regimen.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18 years or older

2. Receiving enteral nutrition via a nasogastric tube or Percutaneous Endoscopic Gastrostomy (PEG)

3. Use of enteral nutrition as main source of nutrition

4. Written informed consent from either patient or legal representative for patients who cannot consent themselves

Exclusion criteria

1. Use of antibiotics in the past 2 weeks

2. Ulcerative colitis or Crohns disease

3. Presence of colostomy

4. Known intolerance or allergy to ingredients of study product

5. Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements

6. Participation in any other study involving investigational or marketed products concomitantly or within two weeks prior to entry into the study

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-10-2008
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-10-2008
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	NL1414
NTR-old	NTR1474
CCMO	NL19190.072.08
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A