

Modulation of gastric function and protein assimilation by different proteins sources in enteral nutrition formulas.

No registrations found.

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

Summary

ID

NL-OMON29207

Source

Nationaal Trial Register

Brief title

Flow study

Health condition

Healthy volunteers

Sponsors and support

Primary sponsor: Danone Research – Centre for Specialised Nutrition

Source(s) of monetary or material Support: Danone Research – Centre for Specialised Nutrition

Intervention

Outcome measures

Primary outcome

The primary parameter in this study is gastric emptying time derived from a mathematical gastric emptying model (MRI).

Secondary outcome

1. Gastric emptying time measured with ¹³C breath test;
2. Changes in postprandial plasma amino acid profile;
3. Volume and dynamics of gastric secretions;
4. Intra gastric distribution and macrostructural changes of the meal;
5. Gastrointestinal symptoms (heartburn, satiety, belching, nausea, vomiting, abdominal distension);
6. Changes in postprandial plasma glucose profiles.

Study description

Background summary

In this study the gastric emptying rate of 3 different enteral nutrition products will be investigated.

Study objective

The primary hypothesis is that tube feeds with different protein sources will have different gastric emptying rates.

Study design

T = 0, 5, 10, 15, 20, 30, 50, 65, 80, 135 and 185 minutes.

Intervention

A single bolus of 300 ml tube feed product will be administered in the stomach with a nasogastric tube. Each subject will receive 3 isocaloric tube feeds with different protein sources in randomized order at 3 separate visits. Repeated MRI scans of the stomach will be done during 185 minutes after product administration. Gastric emptying time will be compared between the 3 products.

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy subjects (male/female);
2. Age between 18 and 50;
3. BMI between 18 and 25 kg/m²;
4. Written informed consent from subject.

Exclusion criteria

1. History of gastrointestinal, cardiorespiratory (including arterial hypertension), hematologic, renal, atopic, alimentary or psychiatric disorder, panic attacks, diabetes, drug or alcohol abuse;
2. Anemia (Hb < 7.5 mmol/l);
3. Requiring medication that might alter gut function, including anticholinergics, calcium channel blockers, beta blockers, laxatives, prokinetics, proton-pump inhibitors, non-steroidal anti-inflammatory drugs;
4. Known galactosemia;
5. Known allergy to one or more of the product ingredients;

6. Positive *Helicobacter pylori* status;
7. Prior abdominal surgery other than uncomplicated appendectomy or hernia repair;
8. Presence of implants, devices or metallic foreign bodies that might interact with the MRI;
9. Claustrophobia;
10. Pregnancy and lactation.

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):	21-07-2011
Enrollment:	20
Type:	Actual

Ethics review

Positive opinion	
Date:	08-07-2011
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	NL2838
NTR-old	NTR2979
Other	Danone Research - Center for Specialised Nutrition : Tub.1.C.B
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A