Gastric versus distal to the ligament of Treitz feeding in healthy volunteers

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Primary objective: To evaluate the differences in digestion and absorption on the administration of enteral nutrition either gastric or distal to the ligament of Treitz in the jejunum.Secondary objective: To evaluate the differences in endocrine...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON36348

Source
ToetsingOnline

Brief title
GuTz study

Condition

- Other condition

Synonym
Zie sectie J

Health condition

Patienten die door hun aandoening of behandeling niet in staat zijn om aan hun voedingsbehoefte te voldoen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Absorption, Digestion, Enteral nutrition, Gastrointestinal hormones

Outcome measures

Primary outcome

The primary parameter in this study is:

- L-[1-13C]phenylalanine

Secondary outcome

Secondary parameters in this study are:

- Amino acid profiles

- Hormone responses: CCK, PYY, ghrelin, GLP-1*, GLP-2*

- Glucose, insulin, C-peptide and glucagon response

- D2-glucose*

- Fatty acid profile in plasma

- Folic acid, vitamin B12, and iron

(* optional)

Parameters on tolerance and safety in this study are:

- Gastric residues by aspiration of gastric content with syringe (every 4h)

- In case of a gastric residue >250 in presence of other signs of intolerance

(ASPEN Guidelines 2009)

- In case of a gastric residue >500ml in absence of other signs of intolerance

(ASPEN Guidelines 2009)

- Tolerance questionnaire (every 4h)

- Liver function: AST, ALT, GGT

- Kidney function: creatinine

- Haematology: red blood cell count (RBC), white blood cell count (WBC),

platelet count, haemoglobin (Hb)

- CRP

- Serum electrolytes: Na, K, Urea

- (Serious) adverse events

Study description

Background summary

Enteral feeding is the preferred method of nutritional support in patients who have a functioning gastrointestinal (GI) tract but cannot maintain an adequate oral intake. Enteral nutrition (EN) preserves the intestinal integrity and prevents mucosal atrophy, and is therefore preferred over parenteral nutrition. There are various ways of administrating EN. In general, the preferred route is gastric feeding. It is considered to be more physiological and the tube is easier to place. Disadvantages of gastric enteral feeding are encountered in patients with delayed gastric emptying and those at risk for aspiration. According to the Guidelines for the Provision and Assessment of Nutritional Support in Therapy in the Adult Critically Ill Patient, gastric residual volumes in the range of 250-400 ml should raise concern and lead to the implementation to reduce the risk of aspiration. Jejunal feeding reduces the aspiration risk, and is therefore the appropriate nutrition for patients at risk of aspiration. Peristaltic transport between the duodenum and jejunum behaves as if the *Ligament of Treitz* were the site of a one-way valve. Jejunal peristalsis is very resistant to spontaneous reversal with reflux of its contents. This phenomenon is considered to protect against aspiration.

What the consequences are of gastric or jejunal feeding with respect to changes in levels of amino acids (AA) and serving the nutritional requirements of the patient is currently unknown. The first proteolyses step of pepsin and gastric acid is skipped when EN is administered in the jejunum. That is why it is

hypothesised that digestion and absorption of AA will be lower when the stomach is bypassed. Still, it is taken into account that casein coagulates in the stomach, and may therefore cause less absorption in the gastrointestinal tract. Therefore, it is proposed that the differences in the responses to gastric and jejunal feeding with a main focus on digestion and absorption of AA will be determined.

Changes in GI response occur after gastric bariatric bypass surgery. Roux-en-Y Gastric Bypass surgery (RYGB) involves anatomical changes, physiology is hence altered. The interplay between food intake and gut function of the altered GI system apparently results in clinical improvement. It has been postulated that this improvement in glycemic control, reduction in appetite, and subsequent weight loss following bypass surgery may be due to changes in circulating gut hormones. By administrating enteral nutrition to the jejunum RYGB is more or less mimicked. For better understanding of hormonal involvement in gastric bariatric bypass surgery, the physiology of GI hormones will be studied in extensive detail. Insight into the relationship of GI hormone response, plasma glucose and pancreatic islet after administration of EN may give us insight in an optimal metabolic support.

Study objective

Primary objective: To evaluate the differences in digestion and absorption on the administration of enteral nutrition either gastric or distal to the ligament of Treitz in the jejunum.

Secondary objective: To evaluate the differences in endocrine responses on the administration of enteral nutrition either gastic or distal to the ligament of Treitz in the jejunum.

Study design

The GuTz study is a randomized, single-blind, single center, cross-over study. The influence of confounding covariates is reduced because each crossover subject serves as his own control. In this study it is not needed to add a control group, because all parameters are influenced by the nutritional intervention, and baseline sampling before the start of the administration of EN is done. Also, a crossover design is statistically efficient and so requires fewer subjects.
To see if there is an order effect the route of administering EN is randomised. This way an order effect will be detected in retrospect. To be sure there is no carry-over effect of the previous visit there will be a sufficiently long wash-out period of four-weeks between the visits.

Intervention

Administration enteral nutrition on the stomach is compared to administrating enterl nutrition distal of de ligament of Treitz in the jejunum.
The intervention is gastric feeding and jejunal feeding with Nutrison Standard Advanced Multi Fiber (Danone Research). Nutricia has developed and marketed a tube feed for patients who cannot maintain an adequate oral intake. It is a complete nutrition, with a specific protein blend opmitised on aminoacid profile, enriched with EPA/DHA, fibres, vitamins and minerals, the levels are based on the guidelines for Food for Special Medical Purposes (FSMP). Nutrison Standard Multi Fibre is a product which is commercially available and has proven to be safe, well tolerated and can be given as a sole nutrition. A multi fibre blend is added several years ago to reduce gastrointestinal intolerance like diarrhea.

Study burden and risks

Blood sampling: subjects may experience pain at the needle puncture site; light-headedness, haematoma; fainting; infection (a slight risk any time the skin is broken).

NGT/NJT: placement of the naso-gastric and naso-jejunal tube can be very unpleasant; retching is a common phenomenon during placement; sore throat; hoarse voice; nosebleeds (in case of multiple nosebleeds the naso-tube will be replaced by an oral-tube); placement of the NGT or NJT will be monitored with X-rays as insertion in the trachea will lead to a severe adverse event when enteral nutrition is started. This is a very rare complication.

Possible adverse effects with enteral nutrition include: belching; nausea; change in stool consistency; diarrhea; abdominal cramps;
There are no other known adverse effects with Nutrison Standard Multi Fibre.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age range: 18 - 45 years
Understanding of the Dutch language
Sex: male
BMI range: 18 - 27 kg/m2
Functioning gastrointestinal tract, eligible for tube feeding via an intestinal tube
Willingness to comply with the study protocol, including:
- Use of standard breakfast day 1 of visit 1 and 2
- Refrain from alcohol consumption 48h prior to, and during the assessments
- Refrain from intense physical activities 48h prior to, and during the assessments
- Refrain from antibiotics, NSAID*s and vitamins 2 weeks prior to, and during the assessments
- Refrain from fish oil 4 weeks prior to, and during the assessments
Written informed consent

Exclusion criteria

Any relevant gastrointestinal medical history, e.g.:
- Major gastrointestinal surgery
- Gastrointestinal disease, e.g.:
- Gastric or paraesophagal hernia
- Gastrointestinal obstruction
- Heartburn
Diabetes mellitus type I and II
Hepatic or renal pathology
Any relevant results of physical exam during screening; defined as:
- Diastolic blood pressure >=130mmHg
- Abnormal heart souffle
- Heart rhythm disorder

- Abnormal respiratory sounds
Any results of laboratory tests during screening other than the normal limit defined by the laboratory (Medial)
Any relevant exclusion criteria listed on the product label; e.g.:
- Subjects requiring a fibre-free diet
Allergy / intolerance for the enteral nutrition
Allergy / intolerance for contrast given during the abdominal X-ray
Smoking, alcohol abuse; defined as:
- Currently smoking or quit <=6 months ago
- > 21 units of alcohol a week
Donor of blood the last 6 months
Any other medical condition that may interfere with the safety of the subjects or the outcome parameters, in the investigator*s judgment
Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol instructions
Participation in any other studies involving investigational or marketed products concomitantly or within two weeks prior to entry into the study

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2011
Enrollment:	12
Type:	Anticipated

Ethics review

Approved WMO Date:	29-04-2011
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	10-06-2011
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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
CCMO	NL34797.094.10