Gastric emptying of a protein and carbohydrate-containing preoperative beverage in patients with a delayed gastric emptying

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Primary Objective To evaluate the gastric emptying time of the protein hydrolysates PRO+CHO beverage in patients with a delayed gastric emptying and compare this with the gastric emptying time of healthy subjects (PrePro1) Secondary Objectives To...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malabsorption conditions
Study type	Observational non invasive

Summary

ID

NL-OMON40788

Source
ToetsingOnline

Brief title
Time of gastric emptying in patients with a delayed gastric emptying

Condition

- Malabsorption conditions

Synonym
Delayed gastric emptying

Research involving
Human

Sponsors and support

Primary sponsor: MDL functieafdeling

Source(s) of monetary or material Support: Alliantie Voeding Gelderse Vallei

Intervention

Keyword: delayed gastric emptying, gastric emptying time, preoperative, protein-carbohydrate beverage

Outcome measures

Primary outcome

The main study parameter is the gastric emptying time of CHO+PRO beverages in patients with a delayed gastric emptying, calculated as the T1/2, Tlag and GEC (gastric emptying coefficient) of the recovery of 13C from breath samples measured continuously for 3 hours after ingestion.

T1/2 indicates the time by which half of the total cumulative recovery of the 13C label is attained, and Tlag designates the time at which the 13CO2 excretion rate reaches its maximal level; while GEC does not have a clear definition, it is only generally used as an overall index of gastric emptying

Secondary outcome

Subjective compliance and preference parameters are measured by a questionnaires. Bloodglucose will be monitored by executing a finger-stick glucose test every hour in patients that are diabetic.

Study description

Background summary

Regarding optimization of preoperative nutrition with a PRO-CHO mixed beverage, the Prepro1 study was conducted in which the time needed for a PRO+CHO beverage, consisting of PeptoPro and Roosvicee, to pass through the stomach was investigated. This study showed that the half-emptying time (t1/2) of the stomach in healthy patients was around 80 minutes and it was recommended to

consume the beverage at least three hours before anaesthesia.
Since patients with a delayed gastric emptying time have higher risk for peri- and postoperative complications it would be interesting to investigate the gastric emptying time of the PRO-CHO mixed beverage in these patients as well. This is done in the PrePro2 safety study where the interval between the intake and operation is determined in order to diminish the chance of aspiration and other complications.
Thus, in this study, the aim is to find out the time needed for the CHO+PRO beverage to pass through the stomach in patients with a delayed gastric emptying.

Study objective

Primary Objective
To evaluate the gastric emptying time of the protein hydrolysates PRO+CHO beverage in patients with a delayed gastric emptying and compare this with the gastric emptying time of healthy subjects (PrePro1)
Secondary Objectives
To find out participants* opinions on the palatability of the drink and their compliance;

Study design

It will be an experimental study. The total duration of the study for each participant will be 2 weeks. 1-2 weeks before starting the experiment, subjects will be screened to check if they comply to the in- and exclusion criteria. When positively screened, subjects can start participating in the experiment. The experiment will be performed in duplo. The experimental trials will be separated by a period of >7 days. Subjects are exposed to 400 ml water with PRO+CHO.

Study burden and risks

There is no direct (health-related) benefit for the participant. Participants can receive a summary of the results with averages of the group after the end of the study.
The breath test measurements is non-invasive (breath test) and risks are therefore minimal. The glucose test might be associated with a little pain as a result of the finger prick.

Contacts

Public
Selecteer

Willy Brandtlaan 10
Ede 6716 RP
NL
Scientific
Selecteer

Willy Brandtlaan 10
Ede 6716 RP
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

A proven delay in gastric emptying

Exclusion criteria

On a prescribed diet that interferes with the study fluids, allergic to milk protein

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2014
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	04-04-2014
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL47844.081.14