Probiotic functionality of several probiotic supplements during gastro-intestinal transit in vivo in healthy human subjects

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Primary objectiveTo measure the conversion rate of mono- and disaccharides into oligosaccharides and mannitol in the digestive tract by the action of food grade micro-organisms Secondary objectivesTo measure pH of gastric and duodenal fluids at...

Ethical review	Approved WMO
Status	Pending
Health condition type	Metabolism disorders NEC
Study type	Interventional

Summary

ID

NL-OMON36265

Source
ToetsingOnline

Brief title
Home-sweet-home project

Condition

- Metabolism disorders NEC

Synonym
Metabolic syndrome, obesity

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Friesland Nutrition,FrieslandCampina;Research

Intervention

Keyword: digestion, Probiotics, sugar fermentation

Outcome measures

Primary outcome

Sugar conversion. This by measuring:

• Fructo- and Gluco-oligosaccharides

• Mannitol

• Sucrose

• Fructose

• Glucose

Secondary outcome

• Phenol red (marker for gastric emptying)

• pH

• Number of viable bacteria

Study description

Background summary

This pilot study aims to reduce the caloric contribution of sugars in a meal by converting mono- and di- saccharides in to oligosaccharides and mannitol in the digestive tract, with the help of enzymes or micro-organisms in a drink. For this, three strains of Lactobacillus reuteri (ATCC55730, DSM17938 and 121), Lactobacillus gasseri BNR17 and two strains of Lduconostoc mesenteroides (ATCC8293 and NCIMB701875) will be used.

Study objective

Primary objective
To measure the conversion rate of mono- and disaccharides into oligosaccharides and mannitol in the digestive tract by the action of food grade micro-organisms

Secondary objectives
To measure pH of gastric and duodenal fluids at different time points
To measure gastric emptying rate of the test drink
To measure the number of viable bacteria at different time points in the stomach and the duodenum, after ingestion of a test drink.

Study design

We will implement a randomised, double-blinded cross-design

Intervention

placement of a naso-duodenal catheter and hereafter consumption of two oral probiotic preparations at two different occasions

Study burden and risks

Placement of catheter involves a small risk of perforation. Positioning of the catheter involves radiation risk equal to a one hour flight in an aeroplane at 4 km altitude

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

sex: male
age: 18-40 years
body mass index 18-30kg/m2

Exclusion criteria

• History of severe cardiovascular, respiratory, urogenital, gastrointestinal/ hepatic, hematological/immunologic, HEENT (head, ears, eyes, nose, throat), dermatological/connective tissue, musculoskeletal, metabolic/nutritional, endocrine, neurological/psychiatric diseases, allergy, major surgery which might limit participation in or completion of the study protocol

Study design

Design

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

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	05-12-2009
Enrollment:	8
Type:	Anticipated

Ethics review

Approved WMO Date:	24-01-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL29748.068.09