Epithelial barrier in obesity

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The aim of this study is to assess differences between lean and morbidly obese subjects in gut permeability, gut microbiota and mucosal inflammation and to assess the effects of weight loss after sleeve gastrectomy on gut permeability, microbiota...

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

Summary

ID

NL-OMON36545

Source
ToetsingOnline

Brief title
Epithelial barrier in obesity

Condition

- Other condition
- Appetite and general nutritional disorders

Synonym
Obesity, overweight

Health condition

morbide obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Gut microbiota, Gut permeability, Inflammation, Obesity

Outcome measures

Primary outcome

Primary Objectives:

• To study whether intestinal permeability differs between morbidly obese patients and lean subjects

• To assess the effects of weight loss after sleeve gastrectomy on gut permeability

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Secondary outcome

Secondary Objectives:

• To study differences in intestinal microbial composition between morbidly obese and lean subjects

• To assess the effects of weight loss after sleeve gastrectomy on gut microbiota.

• To assess immune activation and inflammation in obesity in exhaled air, blood and stool samples

• To assess whether obesity associated changes in permeability are associated with an altered gut microbiota, and with changes in the inflammatory and immune profile

Study description

Background summary

Obesity is an increasing problem in the Western world. Obese subjects show reduced satiety after food intake compared to lean subjects.
In obesity a low inflammory tone is measured, contributing to the development of cardiovascular disease and the metabolic syndrome (hypertension, hypercholesterolemia, insulin resistance etc.). In obese mice the gut permeability is increased resulting of leakage of endotoxins. This further contributes to inflammation. The gut microbiota may mediate this process. The gut microbiota in obese mice extracts more efficiently the nutrients from the food ingested. This has not yet been investigated in obese human subjects.

Gut permeability is likely to be increased in obesity, however, only small studies have been performed in obese human subjects. Gut microbiota in obesity is altered. The microbiota found in obesity is more efficient in extracting energy from nutrients in the gut. After bariatric surgery significant weight loss will occur. After surgery insulin resistance is reduced, cholesterol levels and blood pressure decline.

Either the weight loss or the metabolic changes or both will lead to altered gut microbiota probably supporting weight loss. Small bowel anatomy is unaffected after sleeve gastrectomy. After sleeve gastrectomy tremendous weight loss will occur, enabling us to investigate possible changes of gut microbiota, gut permeability and inflammation due to weight loss and/or metabolic changes.

Study objective

The aim of this study is to assess differences between lean and morbidly obese subjects in gut permeability, gut microbiota and mucosal inflammation and to assess the effects of weight loss after sleeve gastrectomy on gut permeability, microbiota and mucosal inflammation over time.

Study design

The patient group is tested on 3 occasions:
- preoperatively
- 2 months after
- 6 months after

The control (lean) group is only tested during one occasion

Test day:
- 8.00 in the morning: patient reports at the

gastroenterology department
- 8.00-8.15: brief explanation of
the test, subjects are requested to empty their bladder in the toilet
- 8.15: breath sample is
taken, one blood sample is withdrawn (if not performed during routine blood withdrawals)
- 8.15: sugar drink is
ingested, after ingestion of the sugar drink the patient collect the urine at home.
- 8.15- 13.15: urine is collected in
first urine collector
- 8.15-13.15: only water may be
ingested
- 13.15 - 8.15 next day: urine is collected in second
urine collector (delivered to lab afterwards)
- 13.15-8.15: all diets are allowed
- stool samples can be collected at home and delivered at the laboratory afterwards.-

Study burden and risks

Burden for each measurement
- drinking a sugar drink
- first five hours no other diet than water
- collecting urine during 24 hours
- collecting two stool samples
- collecting breath sample
- collecting blood sample (12 ml)

Obese subjects are investigated on 3 occassions, healthy control subjects on one occassion.

Contacts

Public
Catharina-ziekenhuis

Postbus 1350
5602 ZA Eindhoven
NL
Scientific
Catharina-ziekenhuis

Postbus 1350

5602 ZA Eindhoven
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Morbid obese patients candidates for bariatric surgery
Control group consists of age and gender matched lean control subjects.

Exclusion criteria

- Use of antibiotics or infections in the last 4 weeks
- History of gastrointestinal surgery (excl. cholecystectomy/appendectomy)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2011
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	25-03-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL34712.060.11