The relationship of inflammation in adipose tissue and inflammation in blood in patients with morbid obesity and patients with significant weight loss after bariatric surgery.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28337

Source
Nationaal Trial Register

Brief title
ASSISI

Health condition

Morbid obesity
Type 2 diabetes
Cardiovascular disease
Vitamin D deficiency
Morbide obesitas
Diabetes mellitus type 2
Hart- en vaatziekten
Vitamine D deficiëntie

Sponsors and support

Primary sponsor: Sint Franciscus Vlietland Gasthuis
Source(s) of monetary or material Support: Sint Franciscus Vlietland Gasthuis

Intervention

Outcome measures

Primary outcome

To evaluate the effect of bariatric surgery induced weight loss on the relationship between C3 and vitamin D in visceral and subcutaneous adipose tissue and serum.

Secondary outcome

To analyze the relationship between concentrations of C3 and vitamin D in visceral and subcutaneous adipose tissue and serum in morbidly obese subjects scheduled for bariatric surgery

To analyze the relation of vitamin D and C3 with general markers of inflammation and classic cardiovascular risk factors in morbidly obese subjects scheduled for bariatric surgery

To evaluate the effect of weight loss, due to bariatric surgery, on the relation of vitamin D and C3 with general markers of inflammation and classic cardiovascular risk factors
To evaluate the effect of different bariatric procedures on C3 and vitamin D in visceral and subcutaneous adipose tissue and serum

To investigate acute changes (day 1 and day 7 postoperatively) in serum C3 levels in both non-obese and (morbid) obese subjects

Study description

Background summary

Rationale: There is increasing evidence that the immune system is closely linked to metabolic pathways regulating adipose tissue biology, thereby influencing morbid obesity and obesity-related diseases. However, the precise link between metabolism and immunology remains unknown. Both, complement C3 and vitamin D have been associated to inflammation and metabolism in obesity. Elevated C3 levels are associated with the metabolic syndrome, dyslipidemia and insulin resistance. Unpublished data from our clinic show a negative correlation between C3 and vitamin D. The aim of this study is to investigate the biology of vitamin D and C3 in serum and adipose tissue and to investigate the relation of C3 and C3-resistance with inflammation and metabolism in obese subjects.

Objective: To investigate the relationship between C3 and vitamin D in adipose tissue and serum in morbidly obese subjects and in subjects who lost weight due to bariatric surgery.

Study design: A single center cross-sectional (agreement) and longitudinal (changes due to weight loss) study.
Study population: Obese patients aged 18 or older, scheduled for bariatric surgery or lean and overweight patients aged 18 or older, scheduled for laparoscopic cholecystectomy.
Main study parameters/endpoints: Agreement in perioperative C3 and vitamin D levels in visceral and subcutaneous adipose tissue (VAT, SAT) and serum and changes in both markers after weight loss due to bariatric surgery.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: After informed consent obese subjects will visit the outpatient department to undergo the standard bariatric protocol. Approximately 30 mL of extra blood needs to be collected from each subject during the standard pre- and postoperative venipuncture and one day postoperatively. Extra venipuncture will be performed in both lean and obese subjects on the day of admission and 7 days postoperatively. During preoperative screening and standard follow-up additional echocardiography, IMT and PWV measurements will be performed. During surgery two adipose tissue samples will be collected; one subcutaneous of 3 grams and one visceral sample of 5 grams. No adverse effects are to be expected during the collection of the samples. When participating subjects need to undergo elective cholecystectomy after the bariatric intervention new adipose tissue samples will be collected. The follow-up period will be 5 years.

Study objective

Complement C3 levels are elevated in morbid obesity due to C3-resistance, which is partly mediated by vitamin D deficiency.

Study design

3 months preoperative

1 day preoperative

1 day postoperative

1 week postoperative

3 months postoperative

1 year postoperative and than annually.

Intervention

Collection of visceral and subcutaneous adipose tissue during the bariatric procedure.

Additional blood collection tube, during standard venipuncture.

Intima media thickness measurement pre- and postoperative.

Echocardiography pre- and postoperative.

Contacts

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Eligibility criteria

Inclusion criteria

Scheduled for bariatric surgery, which means BMI > 40 kg/m2 or BMI >35 kg/m2 and obesity related comorbidity.

Ages 18 or above

Informed consent

Exclusion criteria

Previous cholecystectomy

Acute inflammatory disease 6 weeks prior to surgery

Immune modulating therapy 6 weeks prior to surgery

Patients planned for simultaneous bariatric surgery and cholecystectomy.

Previous bariatric surgery.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-04-2015
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-04-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41204
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5026
NTR-old	NTR5172
CCMO	NL47891.101.14
OMON	NL-OMON41204

Study results