Adipose tissue and systemic inflammation; exploring the roles of C3 and vitamin D

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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.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON41204

Source
ToetsingOnline

Brief title
ASSISI study

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
excessive body weight, Morbid obesity

Health condition

Morbide obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Adipose tissue, Bariatric surgery, Inflammation, Morbid Obesity

Outcome measures

Primary outcome

To analyze the effect of weight loss on the relationship between concentrations of C3 and vitamin D in visceral and subcutaneous adipose tissue and serum.

Secondary outcome

To analyze the relation of vitamin D and C3 with general markers of inflammation and classic cardiovascular risk factors in adipose tissue and serum and to analyze the effects of weight loss on these relations. To investigate acute changes in post-operative serum C3 levels in obese and non-obese subjects.

Study description

Background summary

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 Unpublished data from our clinic show a negative correlation between C3 and vitamin D. The aim of this study is to investigate the biology of vitamin D and C3 in serum and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.

Study 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 and longitudinal study.

Intervention

ASSISI-2: vitamin D supplementation versus placebo during a 12 weeks preoperative period.

Study burden and risks

After informed consent obese subjects will visit the outpatient department to undergo the standard bariatric protocol. In the first sub-study, approximately 30 mL of extra blood needs to be collected from each subject during the standard pre- and postoperative venipuncture and one day postoperative. 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 and IMT and PWV measurement 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.

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

Scheduled for bariatric surgery (which means BMI >40 or BMI>35 with comorbidity)
Scheduled for laparoscopic cholecystectomy (BMI <30)
Aged 18 or above
Given Informed consent

Exclusion criteria

Previous cholecystectomy
Any acute inflammatory disease within 6 weeks prior to surgery
Any immune modulating therapy within 6 weeks prior to surgery
Patients planned for bariatric surgery and cholecystectomy 'en bloc'
Patients unable to understand and/or read the given information

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-04-2015
Enrollment:	220
Type:	Actual

Ethics review

Approved WMO

Date:	22-12-2014
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

ID: 28337
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL47891.101.14
OMON	NL-OMON28337