# 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.

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

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|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON28337

**Bron**
NTR

**Verkorte titel**
ASSISI

**Aandoening**

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

## Ondersteuning

**Primaire sponsor:** Sint Franciscus Vlietland Gasthuis
**Overige ondersteuning:** Sint Franciscus Vlietland Gasthuis

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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.

# Toelichting onderzoek

### Achtergrond van het onderzoek

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 Unpublished data from our clinic show a negative correlation between C3 and vitamin D. The aim of this study is to investigate the biology of vitamin D and C3 in serum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

**Doel van het onderzoek**

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

**Onderzoeksopzet**

3 months preoperative

1 day preoperative

1 day postoperative

1 week postoperative

3 months postoperative

1 year postoperative and than annually.

**Onderzoeksproduct en/of interventie**

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.

# Contactpersonen

## Publiek

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |

**Controle:** N.v.t. / onbekend

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 14-04-2015 |
| Aantal proefpersonen: | 200 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 29-04-2015 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41204
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

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

# Resultaten