# *Omega-3 fatty acids in bariatric gastric bypass surgery: effects on liver volume, immune response and erythrocyte function*

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Appetite and general nutritional disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON40548

**Source**
ToetsingOnline

**Brief title**
OLIVIER

### Condition

- Appetite and general nutritional disorders
- Gastrointestinal therapeutic procedures

**Synonym**
excess body weight, Morbid obesity

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Medisch Centrum Alkmaar
**Source(s) of monetary or material Support:** Europese Unie

## Intervention

**Keyword:** bariatric surgery, liver volume, morbid obesity

## Outcome measures

### Primary outcome

The main study parameter is liver volume after pre-treatment with a low calorie

diet compared to pre-treatment with omega-3 fatty acids.

### Secondary outcome

The effect of omega-3 fatty acids on the perioperative immune response and

low-grade inflammatory state in adipose tissue.

The effect of omega-3 fatty acids on the perioperative stress response.

The effect of omega-3 fatty acids on the function of the red blood cell.

The effect of gastric bypass surgery on weight, immune response, stress

response and red blood cell function.

# Study description

### Background summary

Gastric bypass surgery is the gold standard in bariatric surgery and is a successful method to reduce weight in morbidly obese subjects. Patients qualified for gastric bypass surgery are routinely pre-treated with a low

calorie diet in order to reduce liver volume and to facilitate the approach of the gastro-oesophageal junction. Pre-treatment with omega-3 fatty acids has similar effects on liver volume, but a prospective comparison of both treatments has not been performed yet. Morbidly obese patients respond differently to surgical stress, due to a number of factors. First, obesity is associated with a low-grade inflammatory state induced by an increased amount of macrophages in adipose tissue. This state is associated with higher levels of pro-inflammatory cytokines in serum and with a less adequate immune response to infections. Second, obesity is associated with an altered cortisol metabolism possibly related to adrenal insufficiency. This could play an important role in the altered response to surgical stress and postoperative complications in obese subjects. Third, obesity is associated with altered erythrocyte function, including decreased erythrocyte deformability and increased aggregation, factors contributing to an impaired microcirculation.
This study has a number of different aims. First, we will compare pre-treatment with the standard low calorie diet with omega-3 fatty acids on liver volume in patients qualified for gastric bypass surgery because of morbid obesity. Second, we will investigate the effect of omega-3 fatty acids on immune function before and after bariatric surgery. Third, we will investigate the effect of omega-3 fatty acids on the low-inflammatory state of adipose tissue. Fourth, we will assess the effect of omega-3 fatty acids on the stress response of obese subjects before and after the and after bariatric surgery. Fifth, we will investigate the effect of omega-3 fatty acids on erythrocyte function before and after the and bariatric surgery.

## Study objective

Our primary objective is to compare pre-treatment with the standard low calorie diet with pre-treatment with supplemental omega-3 fatty acids on liver volume. Secondary objectives are patient satisfaction about different dietary pre-treatments, the effect of omega-3 fatty acids before and after bariatric surgery on immune function, level of inflammatory state in adipose tissue and function of involved leucocytes, cortisol response, erythrocyte function, and the long term effect of bariatric surgery on immune function and erythrocyte function six months after surgery.
Study design: This study is set up as a randomised controlled open label trial.

## Study design

This study is set up as a randomised controlled open label trial.

## Intervention

Omega-3 fatty acids capsules, twice a day one capsule, during 2 weeks prior to gastric bypass surgery.

**Study burden and risks**

The burden and risks associated with participation are associated with the possible side effects of omega-3 fatty acids and two MRI measurements of liver volume, small risk of additional peroperative blood loss because of abdominal tissue biopsies and collection of venous blood samples at every time point of the study.

# Contacts

**Public**
Medisch Centrum Alkmaar

Wilhelminalaan 12
Alkmaar 1815JD
NL
**Scientific**
Medisch Centrum Alkmaar

Wilhelminalaan 12
Alkmaar 1815JD
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

•Females undergoing laparoscopic gastric bypass surgery because of morbid obesity
•Age between 18 and 65 years

•Written informed consent
•Patient will fit in the MRI-scan based on waist circumference (less than approx. 150cm and body weight less than 200kg)

### Exclusion criteria

•Pregnancy
•Diabetes mellitus type 1
•Current history of inflammatory, infectious or malignant disease
•The use of anti-inflammatory drugs
•Contra-indications for the use of omega-3 fatty acids
•Patient previously underwent bariatric procedures

## Study design

### Design

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| Study phase: | 4 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Prevention |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 12-11-2014 |
| Enrollment: | 62 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Omega 3 fatty acids |
| Generic name: | Omega 3-acid-ethyl esters |

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| Registration: | Yes - NL outside intended use |

## Ethics review

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| Approved WMO Date: | 06-01-2014 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 17-03-2014 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 12-01-2015 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 16-01-2015 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

## 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 |
|---|---|
| EudraCT | EUCTR2013-004750-24-NL |

| Register | ID |
| --- | --- |
| CCMO | NL47021.029.13 |