

# Complications in body contouring surgery.

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To describe the wound related complication rate in post-bariatric body contouring surgery patients who are treated according to a new guideline and assess the factors associated with a higher complication rate.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Ancillary infectious topics
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON43939

### Source

ToetsingOnline

### Brief title

Contour

### Condition

- Ancillary infectious topics
- Appetite and general nutritional disorders
- Skin and subcutaneous tissue therapeutic procedures

### Synonym

skin surplus

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Sint Antonius Ziekenhuis

**Source(s) of monetary or material Support:** volgt

## Intervention

**Keyword:** bodycontouring surgery, nutritional deficiencies, nutritional status, post-bariatric

## Outcome measures

### Primary outcome

Wound related complications within 30 days after body contouring surgery.

### Secondary outcome

Demographics, weight history, bariatric surgery, relevant history, consequences of excess skin, nutritional status, body contouring surgery and other complications.

## Study description

### Background summary

There is a growing population of patients who successfully undergo bariatric surgery and are then eligible for body contouring surgery (BCS). BCS improves patient well-being and quality of life, also it seems to prevent long term weight regain after bariatric surgery. However body contouring procedures have a high risk for wound related complications. Literature assessing the factors that influence the complication rate is sparse and inconclusive. The poor nutritional status, which frequently occurs after bariatric surgery, has been linked to the high complication rate. However improving nutritional status was never part of standard treatment in previous research.

### Study objective

To describe the wound related complication rate in post-bariatric body contouring surgery patients who are treated according to a new guideline and assess the factors associated with a higher complication rate.

### Study design

Prospective descriptive study.

### Study burden and risks

The burden of participation is one extra hospital visit with consultation of dietician and an extra blood sample which is drawn during surgery.

## Contacts

### Public

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koekoekslaan 1  
Nieuwegein 3435CM  
NL

### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- \* post-bariatric patient
- \* undergoing body contouring surgery because of skin surplus
- \* contouring in one of the following regions:
  - abdomen
  - mammae
  - legs
  - arms
  - upper body

lower body

## Exclusion criteria

- \* Body Mass Index (BMI) is higher than 34.9 kg/m<sup>2</sup>
- \* weight not stable in last 12 months
- \* diabetes mellitus defined by currently using either oral medication or insulin
- \* active smoker
- \* using immunosuppressive drugs, e.g. corticosteroids, methotrexate
- \* using anti-coagulants other than acetylsalicylic acid
- \* coagulopathy, vasculitis, connective tissue disorder
- \* kidney-(GFR<30) or liver failure
- bariatric surgery other than Laparoscopic Adjustable Gastric Band, (laparoscopic) Roux-en-Y gastric bypass or (laparoscopic) gastric sleeve

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-11-2015

Enrollment: 160

Type: Actual

## Ethics review

Approved WMO

Date: 30-06-2015

Application type: First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	29-06-2016
Application type:	Amendment
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	NL53259.100.15