Prospective health-related Quality of Life analysis following bariatric surgery patients with or without body contouring surgery using the BODY-Q

Published: 18-08-2017
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Primary Objective: To assess the effect of bariatric and, eventually, subsequent body contouring surgery on appearance and HRQoL over time using the BODY-Q questionnaire.
Secondary Objectives: The secondary objectives are (1) psychometric validation…

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

Summary

ID

NL-OMON45666

Source
ToetsingOnline

Brief title
BODY-Q study

Condition

- Other condition
- Gastrointestinal therapeutic procedures

Synonym
bariatric surgery and body contouring surgery, Obesity

Health condition

Bariatrische chirurgie en body contouring chirurgie bij obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Sint Lucas Andreas Ziekenhuis
Source(s) of monetary or material Support: NVT

Intervention

Keyword: Bariatric surgery, Body contouring surgery, Outcome assessment, Quality of life

Outcome measures

Primary outcome

Main study parameter:

- Differences in mean BODY-Q scores (Δ mean BODY-Q scores) pre-bariatric surgery and (4 and 12 months, 2,3,4,5 years) post-bariatric surgery

- Differences in mean BODY-Q scores (Δ mean BODY-Q scores) pre-bariatric surgery and (3 and 12 months, 2,3,4,5 years) post-body contouring surgery

- Differences in mean BODY-Q scores (Δ mean BODY-Q scores) between patients who demand and not demand for body contouring surgery

- Differences in mean BODY-Q scores (Δ mean BODY-Q scores) between patients who desire and undergo or not undergo body contouring surgery

Secondary outcome

Secondary study parameters:

- Predictive variables of improvements in mean BODY-Q scores (Δ mean BODY-Q scores)

- Predictive domain BODY-Q scores who proceed to body contouring surgery

- Predictive variables of patients who desire body contouring surgery

- Predictive variables of patients who will undergo body contouring surgery

- Long term weight loss with or without body contouring surgery: percentage excess weight loss (%EWL), Percentage total weight loss (%ΔTWL) and change in body mass index (ΔBMI)

Study description

Background summary

Bariatric surgery is considered the most effective treatment option for morbid obesity in the long-term. The substantial weight loss, however, leaves patients with excessive skin, which can have a negative impact on appearance and health-related quality of life (HRQoL). Body contouring surgery has considerable potential to restore these corollaries. Presently, limited data are available documenting appearance and HRQoL in both the bariatric and body contouring population, partly due to the lack of HRQoL measurements for this specific population. Therefore, a longitudinal study is needed to measure HRQoL changes over time during the total weight loss journey. A new patient-reported outcome measure (PROM), the BODY-Q, is the first to cover both types of surgery and has been translated for use in Dutch patients. BODY-Q scales measure appearance (of various body areas), HRQoL, and the patient experience of care. Psychometric validation of the BODY-Q will enable measurement of clinical effectiveness and economic efficiencies from the patients* perspective in the Netherlands. Furthermore, to date surgeons lack precision when predicting which bariatric surgery patients will proceed to body contouring surgery. Additionally, as weight regain negatively impacts patient health and long-term costs in the healthcare system, better evidence is needed on the influence of body contouring surgery on weight control following bariatric surgery. Appropriate prediction of these concerns will enable surgeons to communicate false expectations, improve patient satisfaction and improve consult efficiency. This will be the first nationally representative research on this subject and these data will be needed to inform patient selection and education, comparative effectiveness research, and healthcare policy decisions.

Study objective

Primary Objective: To assess the effect of bariatric and, eventually, subsequent body contouring surgery on appearance and HRQoL over time using the BODY-Q questionnaire. Secondary Objectives: The secondary objectives are (1) psychometric validation of the Dutch translated BODY-Q questionnaire (2) to identify predictive variables correlated with amelioration in BODY-Q scores (3) to identify predictive domain BODY-Q scores correlated with the demand for body contouring surgery (4) to identify predictive variables correlated with the

demand for body contouring surgery (5) to identify predictive variables correlated with patients who undergo body contouring surgery (6) to assess the influence of body-contouring surgery on long-term weight control.

Study design

Multicentre prospective longitudinal cohort study

Study burden and risks

Patients will not have to undergo additional invasive procedures by participating in the present study. Therefore, we anticipate no additional risks by undertaking the present study and no liability insurance is needed.

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

Patients scheduled bariatric surgery in the OLVG West Hospital, Amsterdam; Catharina Hospital, Eindhoven; St. Antonius Hospital, Nieuwegein; the Netherlands.

Exclusion criteria

- Age > 65 years of age < 18 years
- Unable to read Dutch
- Unable to sign informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-11-2017
Enrollment:	738
Type:	Actual

Ethics review

Approved WMO

Date:	18-08-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	24-10-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-11-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-11-2020
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	NL60699.100.17