Feasibility and safety of same-day discharge after Laparoscopic Sleeve Gastrectomy (LSG) in the Netherlands

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The aim of the study is to investigate the feasibility and safety of same-day discharge of laparoscopic Sleeve Gastrectomy in a select group of patients.

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53812

Source
ToetsingOnline

Brief title
BARABAS study (BARiatric AmBulAtory Sleeve gastrectomy)

Condition

- Other condition

Synonym
morbid obesity, severe obesity

Health condition

morbide obesitas

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Ambulatory, Bariatric Surgery, Gastric Sleeve, LSG

Outcome measures

Primary outcome

The primary outcome is the number of patients who are discharged successfully

at the day of the surgery.

Secondary outcome

Complications, mortality, ER-visits, readmissions and re-operations.

Study description

Background summary

In the Netherlands, over 12.000 bariatric procedures are performed annually. Due to an exponential growth of the population with morbid obesity in the last decade, a further increase in eligible patients for bariatric surgery is expected. The introduction of laparoscopic techniques in bariatric surgery and implementation of the ERAS (Enhanced Recovery After Surgery) pathways has considerably reduced hospital admission time. Several studies have shown that shortening of postoperative hospital stay does not affect patient*s short-term safety. It has been proved feasible and safe to perform Gastric Bypass in ambulatory care for a select group of patients.

Study objective

The aim of the study is to investigate the feasibility and safety of same-day discharge of laparoscopic Sleeve Gastrectomy in a select group of patients.

Study design

A feasibility study of 50 cases

Intervention

Included patient will be discharged at the same day of the surgery if they meet a number of criteria (i.e. no abnormalities or complications during surgery or anesthesia, stable vital signs, stable Hemoglobin-level, approval of surgeon and patient). On the first postoperative day, the patient is called by the surgeon; on postoperative day 2 or 3, the patient has a thorough medical checkup at the outpatient clinic.

Study burden and risks

By participation in the present study patients will be discharged on the day of the surgery if they meet a number of (safety)criteria to minimize the risk of complications. The next day, the patient is called by the surgeon. On postoperative day 2 or 3, there is a physical medical examination at the outpatient clinic. Patient is being informed how and when to contact the hospital (24/7) in case of abnormalities.
All bariatric patients have a risk of developing complications, regardless the length of hospital stay. Late recognition of complications may lead to increased morbidity and mortality. Chances of complications are limited if patient feel well and have normal vital parameters at the time of discharge. Through remote monitoring and the scheduled appointments, we still observe the patient, but do it remotely.
This results in a decrease in burden on hospital capacity and an increase of patient satisfaction, by letting patients recover in their own environment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Morbidly obese patients (IFSO criteria of morbid obesity) aged between the 18 and 65 years with a BMI < 50 kg/m2
Primary Laparoscopic Sleeve Gastrectomy
The operation will start before 12.00 PM and is the first, second or third procedure on the bariatric program of the day
Master the Dutch language
Patient is able to understand and use the remote medical devices
Residing within a radius of 45 minutes* drive from the OLVG Hospital, location West
An informal carer is available to be at the patient*s side during the 24 hours following hospital discharge.

Exclusion criteria

Uncontrolled diabetes mellitus or use of insulin, cardiac disease (history of myocardial infarction, heart rhythm disorder) and coagulation abnormalities or use of anticoagulants.
Large abdominal surgeries in the past, including abdominal laparotomy
Disapproval for daycare by anesthesiologist or surgeon

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	03-05-2022
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	18-03-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-04-2023
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	NL80532.100.22