‘Feasibility and safety of same day discharge using live video consultation and remote monitoring in a selected group of bariatric patients’

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27530

Source
Nationaal Trial Register

Brief title
DAY-BAR study

Health condition

Bariatric surgery

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

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

day (proportion of successfully discharged on day one of the total included patients including failed same-day discharged patients) over a period of 6 months. .

Secondary outcome

Other outcomes will be mortality, complication, readmissions rates and patient satisfaction.

Study description

Background summary

In the Netherlands, over 10.000 bariatric procedures are performed annually (1). 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) has considerably reduced hospital admission time to two days (one night in the hospital). Several studies have shown that shortening of postoperative hospital stay does not affect the short-term safety of patients. Bariatric surgery in day care have been described earlier. The aim of the study is to investigate the feasibility of same day discharge supported by live video consultation and remote monitoring in a selected group of bariatric patients.

Study objective

We hypothesize feasibility of same day discharge for bariatric patients, without undermining the safety of the patients.

Study design

0, 10 days, 1 month

Intervention

Eligible patients that meet the criteria of this study will be discharged at the same day of the operation and will receive video consultation and remote monitoring during the following day(s).
Same-day discharge is defined as discharge on the day of the surgical procedure without any overnight hospital stay.

Contacts

Public

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Morbidly obese patients (IFSO criteria of morbid obesity) aged between the 18 and 65 years without significant cardiovascular and/or pulmonary diseases, no previous history of a large abdominal surgery (excluding appendectomy and caesarean section)
2. Laparoscopic gastric bypass (LRYGB)
3. The operation will take place before 11 o'clock
4. Master the Dutch language
5. The surgical procedure is the first or second procedure on the bariatric program of the day
6. Patient is able to understand and use the wearable and application
7. Residing within a radius of a 45 minutes' drive from the OLVG hospital
8. An informal carer needs to be at the patient's side during the 24 hours following hospital discharge.

Exclusion criteria

Exclusion criteria
1. Patients is diagnosed with uncontrolled diabetes mellitus or use of insulin, obstructive sleep apnea (OSA) with an Apnea Hypopnea Index (AHI) above 15 or use of a CPAP, cardiac disease (history of myocardial infarction, heart rhythm disorder) and coagulation abnormalities or anti-coagulant use.
2. Large abdominal surgeries in the past including abdominal laparotomy.
3. Revision bariatric surgery, gastric sleeve, other bariatric procedures

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-07-2020
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	23-04-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48459
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7774
CCMO	NL68730.100.19
OMON	NL-OMON48459

Study results