

# **\*Feasibility and safety of same day discharge using live video consultation and remote monitoring in a selected group of bariatric patients'**

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The aim of the study is investigate the feasibility of same day discharge supported by live video consultation and remote monitoring in a selected group of bariatric patients.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Completed
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## **Summary**

### **ID**

NL-OMON48459

### **Source**

ToetsingOnline

### **Brief title**

DAY-BAR study

### **Condition**

- Other condition

### **Synonym**

morbid obesity, severe overweight

### **Health condition**

(morbide) obesitas patienten

### **Research involving**

Human

## Sponsors and support

**Primary sponsor:** OLVG

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Bariatric patients, Bariatric surgery, Same-day discharge, Telemedicine

## Outcome measures

### Primary outcome

The primary outcome is the number of patient (maximum 50 patients) who are discharged successfully on the same day of the total included patients in 6 months time.

### Secondary outcome

Other outcomes will be complications, ER presentations, readmissions, patient satisfaction and mortality rates.

## Study description

### Background summary

In the Netherlands, over 10.000 bariatric surgeries are performed per year . This number is expected to rise due to the increase of patients with morbid obesity These procedures have proven to be safe with morbidity rates of around 3 percent and mortality rates lower than 1 percent.

Several studies have shown that reducing the hospital admission time after surgery does not affect patient\*s short-term safety. Optimisation of hospital care and shortening of admission time by implementing ERAS (Enhanced Recovery After Surgery) has resulted in a mean hospital stay of two days (one night in the hospital).

The risk of developing surgery related complications is independent of the length of hospital stay but further decreasing the length of stay can delay the detection of these complications. Therefore, it is important to asses if further decrease of the admission time is feasible without affecting the

patient outcome or the quality of health care.

## **Study objective**

The aim of the study is investigate the feasibility of same day discharge supported by live video consultation and remote monitoring in a selected group of bariatric patients.

## **Study design**

A feasibility study of 50 cases.

## **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.

## **Study burden and risks**

By participation in the present study patients will be discharged in the evening on the same day the surgical procedure took place if the clinical conditions permit. The next morning, patients will be monitored by live video consultation combined with remote monitoring of their vital parameters using their mobile phones. Additional next day video consultation and remote monitoring is performed if patients still have complaints. All bariatric patients have a risk of developing signs of a complication regardless of 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. Through video consulting and remote monitoring we give the same care, but do it remotely. This results in increase capacity in for the hospital and increased comfort for the patient recovering in there own environment.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- 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 abdominal surgery (excluding appendectomy and cesarean section)
- Laparoscopic gastric bypass (LRYGB)
- Patient masters the spoken Dutch language
- The surgical procedure is the first or second procedure on the bariatric program of the day
- Patient is able to understand and use the wearable and application
- Residing within a radius of 45 minutes from the OLVG hospital
- A informal carer needs to be at home in the days following surgery.

### **Exclusion criteria**

- Patients diagnosed with uncontrolled diabetes mellitus or use of insulin, obstructive sleep apnea (OSA) with an Apneu Hypopneu 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.
- Patients with a large abdominal surgeries in the past including abdominal laparotomy.
- Patients undergoing a revisional bariatric surgery, gastric sleeve, other bariatric procedures.

;Secondary exclusion criteria

- There were abnormalities or complications during the surgical procedure
- Vital signs are divergent (tachycardia >100 , temperature above 38 Celsius, hypotension) at the end of the afternoon
- The surgeon, resident or junior resident needs to observe the patient another day because of vomiting, pain, wound problems, doubt.

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Completed

Start date (anticipated): 07-07-2020

Enrollment: 50

Type: Actual

### Medical products/devices used

Generic name: Checkme pro device

Registration: Yes - CE intended use

## Ethics review

Approved WMO

Date: 29-05-2019

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 13-11-2019

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

ID: 27530  
Source: NTR  
Title:

### In other registers

Register	ID
CCMO	NL68730.100.19
OMON	NL-OMON27530