Assessment of pre- and postoperative Apnea-Hypopnea Index after Same-Day Discharge bariatric surgery in patients with potentially undiagnosed Obstructive Sleep Apnea

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

Summary

ID

NL-OMON56650

Source
ToetsingOnline

Brief title
DAGBAR study

Condition

- Other condition

Synonym
Obstructive sleep apnea, sleep disordered breathing

Health condition

slaap gerelateerde stoornissen in respiratie

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Betaald door Vitalys.

Intervention

Keyword: Bariatric surgery, OSA

Outcome measures

Primary outcome

Primary endpoint is Apnea-Hypopnea Index.

Secondary outcome

Secondary and tertiary endpoints are 30 days complications rate, and parameters for sleep architecture and sleep related breathing (in minutes and percentages; oxygenation desaturation index (ODI), Rapid eye movement (REM) sleep, deep sleep, light sleep, wake time, REM AHI , Respiratory disturbance index (RDI), Total sleep time, saturation <90%, mean saturation, mean saturation during desaturations, number of desaturations).

Study description

Background summary

Bariatric surgery is a highly effective and sustainable treatment against obesity. Recently there has been a trend towards Same-Day Discharge (SDD) bariatric surgery. SDD bariatric surgery has proven to be safe, when proper discharge criteria are used. However, there is no consensus or guideline for discharge criteria for SDD bariatric surgery. In particular, discharge criteria for patients with obstructive sleep apnea (OSA) diverge between hospitals. In some, but not all hospitals, having (untreated) OSA is a contra-indication for SDD bariatric surgery.

In Rijnstate hospital, bariatric patients are not routinely tested for OSA preoperatively, meaning that they potentially have undiagnosed OSA. Having potentially undiagnosed OSA, is not a contra-indication for SDD bariatric surgery in Rijnstate hospital. Hospitals could be hesitant for SDD bariatric surgery in patients with OSA, because it is known that the apnea hypopnea index (AHI) increases postoperatively. In a population without obesity, the highest postoperative AHI was found during the third postoperative night. During this third postoperative night, patients with a normal postoperative course will already sleep at home, both after inpatient and SDD bariatric surgery. This raises the question whether having (untreated) OSA should be a contra-indication for SDD bariatric surgery. However, it is unknown if the same postoperative changes in AHI and sleep architecture occur in patients undergoing bariatric surgery.

Study objective

The primary objective of this study is to assess postoperative Apnea-Hypopnea Index (AHI) changes during the first and third night after Same-Day Discharge bariatric surgery in patients with potentially untreated OSA. The secondary objective of this study is to compare postoperative AHI changes between patients with a pre-operative AHI of 0-14 or >=15. The tertiary objective of this study is to describe and compare pre- and postoperative sleep architecture.

Study design

This is a prospective observational study. AHI and sleep architecture will be assessed and compared before and after Same-Day discharge (SDD) bariatric surgery during the first and third postoperative night with Home Sleep Apnea Tests.

Study burden and risks

For this study, patients have to fill in two short questionnaires (ESS and STOP-BANG, completion time of maximum 15 minutes) and will undergo three non-invasive Home Sleep Apnea Tests. No extra visits to the hospital or prolonged hospital stay is required during this study. This study cannot be carried out without the selected patient population. If our hypothesis is correct then more patients will be eligible for SDD bariatric surgery, which will be beneficial for both patients and hospitals. Therefore, the potential benefits outweigh the (minimal) burden of this study.

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

- Rijnstate criteria for SDD bariatric surgery:
- Age >=18 years
- During the first postoperative night an adult person (=caregiver) must be
present at the home or residence of the patient, to seek medical attention if needed
- Both patient and caregiver must speak and read the Dutch language
- During the first postoperative night the patients must reside within a 60- minute radius of Rijnstate hospital (Arnhem)
- Undergo primary bariatric surgery (RYGB or SG)
- In possession and able to use a smartphone

Exclusion criteria

- Rijnstate exclusion criteria for SDD bariatric surgery
- Not living in the Netherlands
- Patients from psychiatric wards, inmates of prisons and other state institutions
- Insulin dependent diabetes
- Patients with active implants such as ICD and pacemaker
- Patients using a beta-blocker
- Patients diagnosed with OSA but without treatment
- Revisional bariatric surgery (e.g. sleeve conversion, RYGB after gastric banding)
- Diagnosed OSA with treatment (CPAP, oral appliances)
- Professional drivers
- Use of alpha blockers
- Unable to speak or read the Dutch language
- Not in possession or not able to use a smartphone

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-04-2024
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	20-03-2024

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL86035.091.23