The effect of preventive oxygen therapy on sleep disordered breathing and sleep architecture during the first postoperative night after bariatric surgery

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The primary objective of this study is to assess the effect of preventive oxygen therapy on sleep disordered breathing during the first postoperative night after bariatric surgery. The secondary objective of this study is to observe the effect of...

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

Summary

ID

NL-OMON53186

Source
ToetsingOnline

Brief title
PEAS trial

Condition

- Other condition

Synonym
Obstructief slaap apneu; slaap apneu

Health condition

Slaapstoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Deels door Vitalys en er is een aanvraag voor een bijdrage van het Vriendenfonds van Rijnstate

Intervention

Keyword: Bariatric surgery, OSA, Sleep

Outcome measures

Primary outcome

Aneu hypopneu index

Secondary outcome

30 days complications rate, nursing intervention 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). Score of the Epworth Sleepiness Scale (ESS).

Study description

Background summary

The prevalence of obstructive sleep apnea (OSA) in the bariatric surgery population is high and mostly undiagnosed. The best perioperative strategy to manage sleep apnea in bariatric patients remains unclear. A recent study found that monitoring patients with pulsoximetry and giving them preventive oxygen therapy during the first postoperative night is safe and cost effective. In a

population with patients with OSA but without obesity, no significant difference in apnea hypopnea index (AHI) was found between patients with and without oxygen therapy during the first postoperative night. The question was raised if preventive oxygen therapy during the first postoperative night after bariatric surgery is needed

Study objective

The primary objective of this study is to assess the effect of preventive oxygen therapy on sleep disordered breathing during the first postoperative night after bariatric surgery. The secondary objective of this study is to observe the effect of preventive oxygen therapy on complication rate, nursing intervention rate and sleep architecture. The tertiary objective is to assess the effect of opioid use on AHI and sleep architecture.

Study design

This is a randomized controlled non-inferiority trial consisting of two arms;
Arm A: First postoperative night in the hospital with preventive oxygen therapy (standard care),
Arm B: First postoperative night in hospital without preventive oxygen therapy (intervention).

Sleep related breathing and sleep architecture will be assessed during the first postoperative night with a non invasive sleep test.

Intervention

During the first postoperative night at the hospital patients in arm B will not receive preventive oxygen therapy.

Study burden and risks

Patients are asked to fill in two short questionnaires (ESS and STOP BANG) and will undergo an in hospital sleep test. This sleep test is not invasive. No extra visits to the hospital or prolongation of hospital stay is required for this study. Patients in the intervention arm will not receive oxygen therapy during the first post-operative night in the hospital. We are convinced that this can be done safely, because patients are in a controlled environment (hospital) and will still be continuously monitored. If desaturations occur, the nurse can intervene by for example waking up the patient or can still start with oxygen therapy

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 who undergo primary bariatric surgery (Roux-Y gastric bypass or Gastric Sleeve), Age: >18- years, speak and read the Dutch language

Exclusion criteria

- Revisional bariatric surgery (e.g. sleeve conversion, RYGB after gastric banding), age < 18 years, Diagnosed OSA with treatment (CPAP, oral appliances), Professional drivers, Use of alpha blockers, Unable to speak or read the Dutch language, patients with same-day discharge

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-04-2024
Enrollment:	152
Type:	Actual

Ethics review

Approved WMO

Date:	20-11-2023
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	NL84729.091.23