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Can oxygen delivered into the nose (rather than through a face mask) improve oxygen levels at the start of anesthesia in obese patients undergoing surgery?

Submission date
19/10/2018

Recruitment status
No longer recruiting

Registration date
23/10/2018

Overall study status
Completed

Last Edited
17/11/2023

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Very fat (obese) people have a large belly that presses the lungs upwards and squeezes them, making the lungs smaller. When a person is unconscious due to anesthesia, their breathing is less efficient. This is why obese people have a risk of low oxygen levels in the blood when they are put to sleep before surgery, compared to people with normal weight. The risk of low oxygen continues after the surgery has been completed, when the person is being cared for in the post-operative ward.
This study will compare two different ways of improving oxygen levels in patients undergoing weight loss (bariatric) surgery. The usual way is for the patient to breathe extra oxygen using a face mask. Another way is to deliver the oxygen into the nose. This study aims to recruit 40 patients to compare the two methods. The study's findings should help to find the best way of preventing low oxygen levels.

Who can participate
Adult between 18 and 60 years without serious diseases undergoing weight loss surgery.

What does the study involve?
Participants are asked to join this study before their planned operation. Participants are randomly allocated to one of the two groups. All patients will have an arterial line (needle and tube that stays in the artery) placed in the wrist to make it possible to get blood samples to measure the oxygen content in the blood. Before the start of anesthesia, the participant will breathe oxygen for 5-10 minutes. Blood samples are collected during this time. After surgery blood samples are collected during the first hour at the post-operative ward.

What are the possible benefits and risks of participating?
Placing the arterial line can cause some pain and occasionally minor bleeding. Possible benefits could be a more comfortable way of oxygenating and more careful monitoring in routine practice.

Where is the study run from?
The study is run from Uppsala University Hospital, Sweden and takes place at Samariterhemmets Hospital in Uppsala, Sweden.

When is the study starting and how long is it expected to run for?
October 2018 to December 2019 (updated 03/07/2019, previously: June 2019)

Who is funding the study?
Uppsala Regional Council

Who is the main contact?
1. Associate Professor Peter Frykholm (scientific contact)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2.2

Study information

Scientific Title
Trans-nasal humidified high flow oxygen for preoxygenation in bariatric surgery. A randomized controlled trial

Acronym
Preoxyobes

Study objectives
Morbidly obese patients are more likely to have significant impairment of pulmonary gas exchange and respiratory mechanics. Furthermore, they are at risk of oxygen desaturation more rapidly than non-obese patients during apnea, which occurs when the patient is anesthetized before the trachea is intubated. We hypothesize that high flow humidified nasal oxygen (HFNO) may increase the efficacy of preoxygenation compared to spontaneous breathing though a face mask.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Uppsala Regional Ethics Review Board, 04/04/2018, Dnr 2018-007

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Pre-intubation apnea following anesthesia in obese patients undergoing bariatric surgery

Interventions
Normally in bariatric surgery, the patient is pre-oxygenated during anesthetic induction with 100% oxygen through a face mask until anesthetic induction is completed and the trachea is intubated. After surgery, at the postoperative ward they receive nasal oxygen supply of 2-4 l /min. Half of the patients will be block randomized to be pre-oxygenated with high flow (70 l /min) nasal 100% oxygen during anesthetic induction and postoperatively with 40 l/min 30% oxygen using Armstrong Medical's Peri-Operative Insufflatory Nasal Therapy (POINT) system. The other half will receive the usual oxygenation.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
1. End-tidal oxygen concentration (EtO2) in breath measured at baseline, every 2.5 min until 10 min and after tracheal intubation by the ventilator (Maquet FLOW-i®)
2. Blood gases measured at baseline, every 2.5 minutes until 10 minutes and after tracheal intubation using Abbott's i-STAT®1 portable blood gas analyser. Blood gases are also measured on arrival at the postoperative ward and at 30 and 60 min after arrival.

Secondary outcome measures
1. End-tidal carbon dioxide concentration (EtCO2) in breath measured by the ventilator (Maquet FLOW-i®)
2. Peripheral capillary oxygen saturation (SpO2; a measure of haemoglobin oxygenation in blood) measured using the Draeger Infinity® Delta monitor
3. Heart rate measured using the Draeger Infinity® Delta monitor
4. Blood pressure measured using the Draeger Infinity® Delta monitor
All secondary outcome measures are measured at baseline, every 2.5 min until 10 min and after tracheal intubation.

Overall study start date
07/12/2017

Completion date
15/03/2020

Eligibility

Key inclusion criteria

1. Patients undergoing bariatric surgery due to morbid obesity
2. American Society of Anesthesiologists (ASA) Classification I or II
3. Able to understand participant information sheet and give written consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
1. New York Heart Association (NYHA) Functional Classification >II
2. COPD or asthma causing restrictions in daily activities
3. Restrictive lung disease associated with a reduction of total lung capacity (TLC) of >20%
4. Allergy to any of the anesthetic agents used in the study

Date of first enrolment
23/10/2018

Date of final enrolment
11/02/2020

Locations

Countries of recruitment
Sweden

Study participating centre
Uppsala University Hospital
Dept. of Anaesthesiology and Intensive Care
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Sponsor information

Organisation
Uppsala Regional Council

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Sponsor type
Government

Website
www.lul.se

ROR
https://ror.org/02ybfkh30

Funder(s)

Funder type
Government

Funder Name
Uppsala Regional Council

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/09/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/07/2021	10/09/2021	Yes	No
Results article		18/04/2022	17/11/2023	Yes	No