

# 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?

<b>Submission date</b> 19/10/2018	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/10/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/11/2023	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> 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 Samariterhemmet 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)

Peter.Frykholm@Surgsci.uu.se

2. Dr. Diddi Fors (public contact)

Diddi.Fors@Akademiska.se

## Contact information

### Type(s)

Public

### Contact name

Dr Diddi Fors

### Contact details

Dept. of Anaesthesia and Intensive Care, Uppsala University Hospital.

Uppsala

Sweden

75185

+46186111519

Diddi.Fors@Akademiska.se

### Type(s)

Scientific

### Contact name

Prof Peter Frykholm

### ORCID ID

<https://orcid.org/0000-0001-6402-136X>

### Contact details

Dept. of Anaesthesia and Intensive Care, Uppsala University Hospital

Uppsala

Sweden

75185

+46186110000

Peter.Frykholm@surgsci.uu.se

## Additional identifiers

## Protocol serial number

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 through 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

## Study type(s)

Treatment

## 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(s)**

1. End-tidal oxygen concentration (EtO<sub>2</sub>) 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.

**Key secondary outcome(s)**

1. End-tidal carbon dioxide concentration (EtCO<sub>2</sub>) in breath measured by the ventilator (Maquet FLOW-i®)
  2. Peripheral capillary oxygen saturation (SpO<sub>2</sub>; 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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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

Uppsala

Sweden

75185

## Sponsor information

**Organisation**

Uppsala Regional Council

**ROR**

<https://ror.org/02ybfkh30>

## Funder(s)

**Funder type**

Government

**Funder Name**

Uppsala Regional Council

# Results and Publications

## 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?
<a href="#">Results article</a>		26/07/2021	10/09/2021	Yes	No
<a href="#">Results article</a>		18/04/2022	17/11/2023	Yes	No