

Laryngeal mask vs endotracheal tube for bariatric surgery

Submission date 26/08/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 18/09/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/09/2008	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1615P

Study information

Scientific Title

Comparison study on ventilation with laryngeal mask and with endotracheal tube for bariatric surgery

Study objectives

Ventilation with laryngeal mask results in better recovery profile than ventilation with endotracheal tube in obese patients undergoing bariatric surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This study was approved by the Ethics Committee, Padua Hospital on 25/07/2008.

Study design

Randomised double-blind (patient, evaluating physician) 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Obesity

Interventions

Ventilation with laryngeal mask vs ventilation with endotracheal tube

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Time to independent walking after the end of anesthesia

Secondary outcome measures

1. Ventilatory parameters
2. Postoperative morbidity
3. Patient and surgeon satisfaction

Overall study start date

08/01/2008

Completion date

08/01/2011

Eligibility

Key inclusion criteria

1. Both males and females, age >18 years
2. American Society of Anaesthesiologists (ASA) classification I-III
3. Obese patients (body mass index [BMI] >30) undergoing bariatric surgery
4. Written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

124

Key exclusion criteria

1. Psychiatric disorders
2. Drug abuse
3. Known or possible pregnancy
4. Previous airway pathology
5. Pulmonary diseases
6. History of gastro-oesophageal reflux

Date of first enrolment

08/01/2008

Date of final enrolment

08/01/2011

Locations

Countries of recruitment

Italy

Study participating centre

Istituto di Anestesiologia

Padova

Italy

35121

Sponsor information

Organisation

Department of Pharmacology and Anaesthesiology, Padua University (Italy)

Sponsor details

c/o Prof Carlo Ori

Istituto di Anestesiologia

Dipartimento di Farmacologia e di Anestesiologia

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Padova

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35121

Sponsor type

University/education

Website

<http://www.istar.unipd.it>

ROR

<https://ror.org/00240q980>

Funder(s)

Funder type

University/education

Funder Name

Department of Pharmacology and Anaesthesiology, Padua University (Italy)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration