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Laryngeal mask vs endotracheal tube for bariatric surgery

Submission date	Recruitment status	[ ] Prospectively registered
26/08/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/09/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/09/2008	Nutritional, Metabolic, Endocrine	[ ] 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 tuber

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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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