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Pressure support ventilation during general anaesthesia

Submission date	Recruitment status	[_] Prospectively registered
26/10/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/11/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/01/2015	Surgery	

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
L94/10/04

Study information

Scientific Title

The effects of pressure support ventilation on emergence time and ventilatory function in comparison to volume controlled ventilation and spontaneous breathing: a randomised study

Study objectives
Pressure support ventilation (PSV) used with laryngeal mask airway during general anaesthesia (GA) permitted to reduce general anaesthesia emergence time and propofol consumption, compared to spontaneous breathing (SB) and controlled mechanical ventilation (CMV). An improvement in ventilatory parameters and a decrease in laryngeal mask airway (LMA) leaks were also observed with PSV.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local medical ethics committee (CPP Sud Mediterannée IV, Hôpital Lapeyronie, CHRU Montpellier) approved on the 28th October 1994 (ref: L94/10-04)

Study design
Prospective randomised comparative three group 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
Mechanical ventilation

Interventions
SB-group: patients underwent SB throughout the ventilator circuit
CMV-group: patients underwent CMV (expiratory tidal volume: VTe of 8 mL/kg, a respiratory rate (RR) of 10 breaths/min and an inspiratory/total duty cycle (Ti/Ttot) ratio of 1:3 with a time plateau pressure at 15% of the inspiratory time)
PSV-group: patients underwent PSV (PSV level was set to obtain a VTe between 7 - 8 mL/kg and RR between 10 - 16 c/min, inspiratory trigger was fixed at -2 cm H2O)

Ventilation was performed with zero positive end expiratory pressure in all three groups. All data were recorded at baseline (T0: before GA induction), 10 min after GA induction (T1), at the surgical incision (T2), at the end of anaesthetic drugs infusion (T3) and when the patient was totally awake (T4). Drugs consumption during GA and duration of GA were recorded at the end

of the surgical procedure. Hemodynamic (HR, MAP) and ventilatory variables (RR, VTi, VTe, Ti /Ttot, plateau pressure, SpO2, PetCO2) were recorded during a 2-min stable state for each period. Peak pressure, plateau pressure and flow were measured with Capnomac Ultima at the tube opening. Airway leaks were determined by noting the difference between inspired and expired tidal volume (VTi-VTe). Airway occlusion pressure (P 0.1) 37 was measured at each point except in T1, T2 and T3 for the CMV group. For T0 and T4, ventilatory variables were obtained in awake patients spontaneously breathing through the circuit via a mouth piece with a nose clip.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
1. LMA removal time, determined by repeatedly (every minute) questioning the patient
2. Emergence time, defined as the time to obtain a 10 point score on a five questions test

Secondary outcome measures
1. Propofol consumption
2. Ventilatory function
3. Adverse effects

Overall study start date
01/01/2005

Completion date
01/01/2009

Eligibility

Key inclusion criteria
1. Patients aged 18 - 75 years, either sex
2. American Society of Anaesthesiologists (ASA) grade I - II
3. Scheduled for elective knee arthroscopic surgery under total intravenous anaesthetic (TIVA) with a LMA and mechanical ventilation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

12 patients

Key exclusion criteria
1. Morbidly obese patients (body mass index [BMI] greater than 35 kg/m^2)
2. Chronic obstructive pulmonary disease (COPD) patients
3. Asthmatic patients
4. Less than 18 years old and more than 75 years old

Date of first enrolment
01/01/2005

Date of final enrolment
01/01/2009

Locations

Countries of recruitment
France

Study participating centre
SAR A, Lapeyronie University Hospital
Montpellier
France
34295

Sponsor information

Organisation
Lapeyronie University Hospital (France)

Sponsor details
295 Avenue du Doyen G Giraud
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03xzagw65

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Lapeyronie University Hospital and Montpellier School of Medicine (France)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/12/2014		Yes	No