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The effects of inhaled anaesthetics on the resistance of the airway of patients subjected to general anaesthesia

Submission date 28/02/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/03/2011	**Overall study status** Completed	
Last Edited 21/01/2019	**Condition category** Respiratory	

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
N/A

Study information

Scientific Title
Respiratory resistance during anaesthesia with isoflurane, sevoflurane and desflurane

Study objectives
1. To investigate the effects of 1.0 and 1.5 MAC desflurane, isoflurane and sevoflurane on total inspiratory resistance (Rrs) and its components during 30 min administration in patients with healthy lungs undergoing general anaesthesia after induction with propofol which does not affect bronchial tone.
2. To investigate the effects of 1.0 and 1.5 MAC desflurane, isoflurane and sevoflurane on total inspiratory resistance (Rrs) and its components during 30 min administration after induction with thopental which may increase bronchial tone.

Our primary hypothesis is that desflurane at high concentrations will cause an increase of respiratory resistance partially due to increased density of the inspired gas mixture.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study has been approved by the Scientific and the Ethics Committee of the University Hospital of Heraklion, Crete, Greece on 22/10/2003 , reference number: 10981

Study design
Randomised 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
Airway resistance in patients with healthy lungs undergoing general anaesthesia

Interventions
Two different induction agents (propofol and thiopental) and three different inhaled anaesthetics (isoflurane, desflurane and sevoflurane) at two different concentrations.

In first group, anaesthesia will be induced with propofol 2mg kg-1, remifentanil 0.1 mcg kg-1 and 0.2 mg kg-1 cisatracurium. All patients will be intubated under direct laryngoscopy with a 7.5 mm cuffed endotracheal tube (ETT) and mechanically ventilated with volume control ventilation (Primus, Draëger Medical, Lübeck, Germany) as follows:

Tidal volume (VT) 7ml Kg-1 of ideal body weight, respiratory rate 10 breaths.min-1, positive end-expiratory pressure (PEEP) 5 cmH2O, inspiratory plateau time (time of inspiratory hold) equal with 50% of total inspiratory time and fresh gas flow (FGF) 5 L.min-1. A screen pneumotachograph with a differential pressure-based flow sensor (RSS100-HR; Hans Rudolph, Kansas City, MO) and a pressure transducer will be inserted between the endotracheal tube and the Y piece of the respiratory circuit, for the measurement of flow and tidal volume and inspiratory pressures respectively. At the beginning of the study a first baseline measurement was obtained after endotracheal intubation and initiation of mechanical ventilation, before the administration of the volatile agents. Thereafter, anaesthesia was maintained with 1 MAC end tidal concentration of sevoflurane, isoflurane or desflurane. Measurements of flow and pressures were recorded for five consecutive breaths every five minutes for thirty minutes at 1 MAC steady state. Subsequently, the inhaled agent will be turned off and two further measurements of flow and airway pressures will be recorded, when end tidal concentrations reach 0.5 and 0 MAC. A second baseline measurement will be obtained after the first series of recordings at 1 MAC were conducted, the volatile agent was turned off and the end tidal concentration of the volatile was zeroed. After the second baseline measurement the volatile agent will be turned on to achieve 1.5 MAC. The same sequence of recordings at 1.5 MAC steady state and following the discontinuation of the agent at 0.5 and 0 MAC were conducted.

In the second group of patients the same series of measurements will be obtained but the induction to anaesthesia will be performed with thiopental 5mg kg-1, remifentanil 0.1 mcg kg-1 and 0.2 mg kg-1 cisatracurium.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Isoflurane, sevoflurane, desflurane

Primary outcome measure
Effects on:
1. Total inspiratory resistance (Rrs) and its components
2. Minimal resistance (Rmin)
3. Effective resistance (DRrs)

Total inspiratory resistance (Rrs) will be calculated every 5 min using the inspiratory hold maneuver. During the end - inspiration flow pause, the static airway pressure waveform has a characteristic trend, with the highest peak at end-inspiration [Pmax], followed by a rapid drop after the zeroing of flow [P1] and a slow decay until a plateau is reached [Pplat].

The accuracy of the results requires passive conditions therefore all patients were paralysed under deep anaesthesia. Total inspiratory resistance (Rrs) and its components, minimal resistance (Rmin) and effective resistance (DRrs) were calculated according to the equations: Rrs = [Pmax Pplat] / V, Rmin = [Pmax P1] / V, DRrs = [P1- Pplat] / V, where V denotes flow.

Rmin reflects mainly airway and endotracheal tube resistance and denotes the flow dependent component of Rrs. DRrs represents two phenomena, time - constant inhomogeneities within the lung and the viscoelastic behaviour of the pulmonary tissues and chest wall. Respiratory values will be expressed as the mean of five consecutive breaths.

Secondary outcome measures
1. The baseline total inspiratory resistance (Rrs) and its components, minimal resistance (Rmin) and effective resistance (DRrs), between the two groups, propofol and thiopental groups to examine whether the induction with thiopental is associated with increased respiratory resistance
2. In the propofol group: the effects of the three different agents at two different concentrations on respiratory resistance and its components
3. In the propofol group: the effect of the duration of the administration of the aforementioned agents (time effect)
4. In the thiopental group: the effects of the three different agents at two different concentrations on respiratory resistance and its components.
5. In the thiopental group: the effect of the duration of the administration of the aforementioned agents (time effect)

Overall study start date
01/11/2006

Completion date
01/12/2012

Eligibility

Key inclusion criteria
All patients aged 18 to 75 years old, scheduled for elective non abdominal, non thoracic surgery under general anaesthesia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
16 patients per group, 12 groups

Key exclusion criteria
History of asthma, chronic obstructive pulmonary disease (COPD) or malignant hyperthermia, as well as previous treatment with bronchoactive drugs (ß-agonists or antagonists, theophylline, anticholinergics and corticosteroids).

Date of first enrolment
01/11/2006

Date of final enrolment
01/12/2012

Locations

Countries of recruitment
Greece

Study participating centre
Livadias 11a
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Sponsor information

Organisation
Department of Anaesthesiology, University Hospital of Heraklion (Greece)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0312m2266

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Department of Anaesthesiology, University Hospital of Heraklion (Greece)

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	01/06/2006		Yes	No
Results article	results	01/09/2011	21/01/2019	Yes	No