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Comparison of the standard polyvinyl chloride tracheal tubes and the straight reinforced tracheal tubes for tracheal intubation through different sizes of the Airtraq™ laryngoscope in anesthetised and paralysed patients

Submission date 09/03/2009	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/03/2009	**Overall study status** Completed	
Last Edited 30/03/2009	**Condition category** 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
anesth2008/01

Study information

Scientific Title
Comparison of the standard Polyvinyl chloride tracheal tubes and the straight reinforced tracheal tubes for tracheal intubation through different sizes of the Airtraq™ laryngoscope in anesthetised and paralysed patients; a prospective randomised study

Study objectives
We compared the intubation success rate of straight reinforced tracheal tubes emerging from the Airtraq™ laryngoscope (AL) (Prodol Meditec SA, Spain) with the standard polyvinyl chloride (PVC) tracheal tubes in anesthetised and paralysed patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
General Hospital of Athens Ethics Committee, approved on 15/06/2008 (ref: 2008/98).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Tracheal intubation

Interventions
The study was conducted in the General Hospital of Athens from March 2007 to January 2009. In total, 347 participants were enrolled into the study.

The participants were randomly allocated (using sealed envelopes) to the following three arms:
1. Intubation with PVC tracheal tubes (PVCT)
2. Intubation with standard wire-reinforced tracheal tubes (RFT)
3. Intubation with silicone wire-reinforced tubes (RFST)

Two sizes of AL were available (7.0-8.5 ID and 6.0-7.5 ID). The sizes of AL and tracheal tube were chosen according to the weight, height and sex of each patient.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
1. Rate of successful intubation
2. Impact of AL size, tube size and type on intubation angle

Secondary outcome measures
Factors affecting successful intubation with straight reinforced tubes through the Airtraq™ laryngoscope.

Overall study start date
01/03/2007

Completion date
01/01/2009

Eligibility

Key inclusion criteria
1. Both males and females, aged 22-75 years
2. American Society of Anesthesiologists (ASA) physical status I-III
3. Scheduled for surgical procedures requiring tracheal intubation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Increased risk or history of difficult intubation
2. History of gastric aspiration
3. History of relevant drug allergy

Date of first enrolment
01/03/2007

Date of final enrolment
01/01/2009

Locations

Countries of recruitment
Greece

Study participating centre
Department of Anaesthesia
Athens
Greece
11475

Sponsor information

Organisation
General Hospital of Athens (Greece)

Sponsor details
c/o Prof Vasilios Dimitriou
Department of Anaesthesia
154, Mesogion Avenue
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Greece
11475

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
General Hospital of Athens, Department of Anaesthesia (Greece)

Funder Name

Nutri Medica (representative of Prodol Ltd in Greece) provided the Airtraq™ devices free of charge for use in the study

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