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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

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