

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 anaesthetised and paralysed patients

Submission date 09/03/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/03/2009	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 30/03/2009	Condition category Surgery	☐ Individual participant data ☐ 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration