Trial to compare the Airway Management Device (AMD) with the Classic Laryngeal Mask Airway™

Submission date	Recruitment status	Prospectively registered		
12/09/2003	No longer recruiting	Protocol		
Registration date	Overall study status	Statistical analysis plan		
12/09/2003	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
06/03/2009	Surgery			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number N0212075199

Study information

Scientific Title

Study objectives

To compare the performance of the Airway Management Device (AMD) with the Classic Laryngeal Mask Airway™ during insertion, maintenance and removal in anaesthetised adult patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics Committee of Royal United Hospital Bath approved the study

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Surgery: Anaesthesia

Interventions

Airway Management Device versus the Classic Laryngeal Mask Airway™ during surgery in anaesthetised patients.

Intervention Type

Device

Phase

Not Applicable

Primary outcome(s)

Success of airway placement

Key secondary outcome(s))

- 1. Time to achieve an airway
- 2. Airway manipulations required
- 3. Complications during use
- 4. Fibre-optic assessment of airway positioning

Completion date

30/04/2003

Eligibility

Key inclusion criteria

Adult patients undergoing surgery requiring general anaesthetic which would normally involve using LMA

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

- 1. Any pathology of the neck or the upper respiratory or upper alimentary tract
- 2. At risk of pulmonary aspiration of gastric contents
- 3. Weight less than 50 kg or greater than 100 kg

Date of first enrolment

01/09/2000

Date of final enrolment

30/04/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Department of Anaesthetics

Bath United Kingdom BA1 3NG

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Royal United Hospital Bath NHS Trust (UK)

Results and Publications

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	01/11/2003		Yes	No