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

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Success of airway placement

Secondary outcome measures

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

Overall study start date
01/09/2000

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

Age group
Adult

Sex
Both

Target number of participants
100

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
England

United Kingdom

Study participating centre

Department of Anaesthetics
Bath
United Kingdom
BA1 3NG

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Royal United Hospital Bath NHS Trust (UK)

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	01/11/2003		Yes	No