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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>		
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

Dr T Cook

#### Contact details

Department of Anaesthetics Royal United Hospital Bath & North East Somerset Council Bath United Kingdom BA1 3NG

## 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