Clinical evaluation of the Portex single use laryngeal mask airway in paediatric anaesthesia: a randomised controlled study with the Intavent "classic" laryngeal mask airway

Submission date	Recruitment status No longer recruiting	Prospectively registered		
30/09/2004		Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/09/2004	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
18/11/2009	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0012134103

Study information

Scientific Title

Study objectives

The primary objective is to establish whether single use Portex laryngeal mask airway performs at least as well as the Intavent 'classic' laryngeal mask airway

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

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

- 1. Single use Portex laryngeal mask
- 2. Intavent 'classic' laryngeal mask

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

Securing a safe airway

Secondary outcome measures

Number of insertion attempts, time to satisfactory insertion, ease of insertion, presence of a post op sore throat

Overall study start date

26/09/2003

Completion date

25/03/2004

Eligibility

Key inclusion criteria

Patients undergoing elective surgery

Participant type(s)

Patient

Age group

Child

Sex

Not Specified

Target number of participants

Added 18/11/09: 40

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

26/09/2003

Date of final enrolment

25/03/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

PICU London United Kingdom WC1N 3JH

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

Great Ormond Street Hospital for Children NHS Trust/Institute of Child Health (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	01/02/2005		Yes	No