ISRCTN07684370 https://doi.org/10.1186/ISRCTN07684370

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