

A comparison of the laryngeal mask airway (LMA) with the facemask and oropharyngeal airway for manual ventilation by PAediatric Ward nurseS in children

Submission date 07/11/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 03/04/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/03/2012	Condition category Respiratory	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Sponsor ref: 5339

Study information

Scientific Title

Acronym

PAWS 2

Study objectives

Does the laryngeal mask airway (LMA) have a superior efficacy to achieve manual ventilation compared with the current recommended technique (the oro-pharyngeal airway and face mask) for children who are not breathing when used by paediatric ward nurses?

Please note that this trial is a follow-on from the previously registered trial ISRCTN38042170 - A comparison of the laryngeal mask airway with the oropharyngeal airway and facemask to achieve manual ventilation in children as performed by critical care and anaesthetic nurses (see <http://www.controlled-trials.com/ISRCTN38042170>), which investigates the LMA used by critical care and anaesthetic nurses.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Oxfordshire Research Ethics Committee A on the 10th September 2007 (ref: 07/H0604/76).

Study design

An interventional un-blinded, randomised single centre study.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Manual ventilation

Interventions

The child would be anaesthetised in a standard way by a consultant anaesthetist. Once asleep the paediatric ward nurse would insert each airway device in random order and manually ventilate the lungs for a minimum of five breaths. Ventilation would be measured by an ultrasonic displacement device sited over the chest and compared to that achieved by the consultant paediatric anaesthetist. There is no follow up after the intervention.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Chest expansion (as a percentage of that achieved by the consultant paediatric anaesthetist, averaged over five breaths), measured at the time of the intervention.

Key secondary outcome(s)

1. To assess the effectiveness of ventilation by paediatric ward nurses when using the facemask and oropharyngeal airway
2. To assess whether the paediatric ward nurses can be trained to successfully place the laryngeal mask airway in anaesthetised children after mannikin training
3. To assess whether a learning curve exists for successful insertion of the laryngeal mask airway
4. To compare the time taken to successful ventilation using both airway devices

All outcomes will be measured at the time of the intervention.

Completion date

24/12/2008

Eligibility

Key inclusion criteria

1. All children aged 6 months to 8 years, scheduled for elective surgery or a magnetic resonance imaging (MRI) scan in which a laryngeal mask airway would be placed routinely
2. Paediatric ward nurses

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 months

Upper age limit

8 years

Sex

All

Key exclusion criteria

1. Children in whom a laryngeal mask airway is contradicted, e.g., gastro-oesophageal reflux disease, known difficult airway or obesity
2. Children outside the inclusion age range

Date of first enrolment

24/09/2007

Date of final enrolment

24/12/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Kadoorie Centre, Level 3

Oxford

United Kingdom

OX3 9DU

Sponsor information

Organisation

Oxford Radcliffe Hospitals NHS Trust (UK)

ROR

<https://ror.org/03h2bh287>

Funder(s)

Funder type

Charity

Funder Name

Resuscitation Council (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				

[Results article](#)

01/08/2007

Yes

No