# 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	Recruitment status	Prospectively registered
07/11/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
03/04/2008	Completed	[X] Results
Last Edited	Condition category	Individual participant data
28/03/2012	Respiratory	

## 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

#### 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 Septermber 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

Results article01/08/2007YesNoParticipant information sheetParticipant information sheet11/11/202511/11/2025NoYes