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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/04/2008	**Overall study status** Completed	
Last Edited 28/03/2012	**Condition category** Respiratory	

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

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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.

Overall study start date
24/09/2007

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

Age group
Child

Lower age limit
6 Months

Upper age limit

8 Years

Sex
Both

Target number of participants
35 nurses, 105 children

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
England

United Kingdom

Study participating centre
Kadoorie Centre, Level 3
Oxford
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Sponsor information

Organisation
Oxford Radcliffe Hospitals NHS Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.oxfordradcliffe.nhs.uk/home.aspx

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Charity

Funder Name
Resuscitation Council (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	01/08/2007		Yes	No