



CHILDREN'S & WOMEN'S HEALTH CENTRE OF BRITISH COLUMBIA

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SUBJECT INFORMATION AND CONSENT FORM

Title of Study:

Evaluation of the Intubating Laryngeal Airway in Children

Principal Investigator:

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Co-Investigators:

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1. INTRODUCTION

You are invited to have your child participate in this study because he/she is undergoing a procedure that requires an airway device that will help him/her breathe while under general anesthetic. We are investigating a specific type of airway device, called the intubating laryngeal airway.

2. YOUR PARTICIPATION IS VOLUNTARY

Your child's participation is entirely voluntary, so it is up to you to decide whether or not to have your child participate. Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to your child during the study and the possible benefits, risks and discomforts.

If you do decide to have your child participate, you will be asked to sign this form. You are still free to withdraw at any time.

If you choose not to be involved or to withdraw your child from the study, you do not have to tell us why. The medical care that your child will receive will not be any different or less than the care he/she would normally receive. Please take time to read this information and ask any questions that may help you understand the study before you decide whether to be in the study or not.

3. BACKGROUND

Most children at British Columbia Children's Hospital undergoing procedures with general anesthesia will require an airway device to help them breathe. The laryngeal mask airway (LMA) is a minor airway intervention that is routinely used during anesthesia.

The LMA was first introduced in 1986 and has revolutionized airway management in anesthesia. As well as use in routine, straightforward airway management, it has the potential for other applications. These include using it as a rescue airway device in emergency situations and as a "bridging" device, to help establish more major airway interventions, such as inserting a breathing tube (endotracheal tube).

In general, using the LMA to manage more complex airways in children is not well researched. This may be because the range of pediatric LMA devices is limited by both a lack of very small sizes and differences in three-dimensional anatomy between young children and adults.

The original LMA design (the "Classic" LMA) has been commercially modified a number of times in an attempt to improve various aspects. The ProSeal LMA provides a better seal around the throat in children than the Classic, but is difficult to insert an endotracheal tube through. The Intubating LMA can be used to insert an endotracheal tube but is not available in children's sizes. Sometimes, a special camera, called a fiberoptic bronchoscope may be used in order to help the anesthesiologist visualize the airway and place airway devices properly. An LMA device that allows the passage of a fiberoptic bronchoscope and then endotracheal tube placement would be especially beneficial.

The Air-Q® Intubating Laryngeal Airway (ILA) is a special kind of LMA with certain modifications that allow it to be used both as a primary airway and as a device that may safely allow the insertion of an endotracheal tube (aided by a fiberoptic bronchoscope). It is designed to be used in both children and adults. There are four children's sizes. Although they are commercially available, their

performance, reliability and design need to be tested rigorously in the clinical setting.

4. WHY IS THIS STUDY BEING DONE?

This study will help us evaluate the performance of the ILA, a promising new airway device, provided to us by Cookgas®, the manufacturer. Although the company is providing the devices, they don't have any input into the study design. We are conducting this study independently and out of interest for maintaining the highest standard of care possible for our patients.

We will be looking at features such as ease of placement, quality of ventilation, pressure, seal and quality of fiberoptic bronchoscope view through the ILA. This is the first stage, or pilot, of a larger study. Pilot studies gather information that helps refine future study designs.

5. WHO CAN PARTICIPATE IN THE STUDY?

In order to participate in the study, your child must be undergoing routine surgery where an LMA is needed for airway management. Your child's anesthesiologist will make this judgement.

6. WHO SHOULD NOT PARTICIPATE IN THE STUDY?

Children should not participate in this study if they have gastroesophageal reflux disease (severe heartburn), significant problems with breathing, disorders that prevent blood from clotting normally, irregular airway anatomy or a history of adverse reaction to the LMA (e.g. allergy to a component).

5. WHAT DOES THE STUDY INVOLVE?

The study is taking place in the operating rooms of British Columbia Children's Hospital. We will recruit 120 children for this study.

Your child will be assessed as meeting the inclusion criteria and the method of airway management will be decided by his/her anesthesiologist. He/she will fall asleep in the operating room with the help of either a drug given through an intravenous catheter (IV – a small skinny plastic tube in the vein) or by gas (both these methods are the usual practice in our hospital). All standard monitors will be attached as for any general anesthetic.

After your child is asleep, one of the study anesthesiologists will insert the appropriately sized ILA to help him/her breathe. Once the ILA is safely placed and your child is breathing normally the anesthesiologist will formally evaluate the airway's performance. Any changes made to the airway during your child's procedure will also be recorded. Throughout this study, a standard LMA device will be ready to use in the unlikely event that the anesthesiologist decides to

replace the ILA. In addition, and as is currently standard practice, when any LMA technique is used, age- and size-appropriate endotracheal tubes and emergency airway drugs will be immediately available.

Once the surgery is over, the airway device will be removed (as is normally the case) at your child's anesthesiologist's discretion. The quality of your child's anesthetic care will not change due to this study.

6. WHAT ARE THE POSSIBLE HARMS AND SIDE EFFECTS OF PARTICIPATING?

There are no new drugs being used in this study. Involvement in this study will not place your child at any greater risk than for any procedure under general anesthesia requiring airway management. The ILA has the same side effects as other LMA devices, which will be used if your child does not participate. The commonest side effect of LMA insertion is a sore throat. Uncommon side effects include regurgitation, vomiting, gagging, hiccups, coughing, mild trauma, abrasion to the mouth or throat and/or bleeding.

7. WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

There are no direct benefits to your child's participation in this study. The information we obtain from the study will be used to advise anesthesiologists on the potential for ILA use in children and its suitability for both routine and difficult airway management. There is no financial reimbursement for participation.

8. WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

Your child's participation in this research is entirely voluntary. You may withdraw your child from this study at any time. You do not have to give reasons for your withdrawal. If you decide to enter your child in the study and withdraw at any time in the future, there will be no penalty or loss of benefits to which you and your child are otherwise entitled, and your child's future medical care will not be affected.

Given the nature of this study, please note that you will not have the opportunity to withdraw your child from this study after he/she has fallen asleep in the O.R. During this time, your child will be cared for by the attending anesthesiologist and will be withdrawn at the anesthesiologist's discretion if it is in your child's best interest.

If you choose to enter the study and then decide to withdraw at a later time, all data collected about your child during his/her enrolment in the study will be retained for analysis. By law, this data cannot be destroyed.

9. WHAT HAPPENS IF SOMETHING GOES WRONG?

By signing this consent form you are in no way waiving your or your child's legal rights or releasing the investigator or anyone else from their legal and professional responsibilities.

10. CAN MY CHILD BE ASKED TO LEAVE THE STUDY?

The study doctor(s)/investigators may decide to discontinue the study at any time, or to withdraw your child from the study at any time, if they feel that it is in your child's best interests.

11. WHAT WILL THE STUDY COST ME?

There will be no additional cost to you for your child's participation in the study. You will not be charged for any research procedure. You or your child will not receive any remuneration/reimbursement for participation.

12. WILL MY CHILD'S PARTICIPATION IN THIS STUDY BE KEPT CONFIDENTIAL?

Your child's confidentiality will be respected. No information that discloses your child's identity will be released or published without your specific consent to the disclosure.

Research records and medical records identifying your child may be inspected, in the presence of an Investigator or his or her designate, by representatives of the UBC Clinical Research Ethics Board, for the purpose of monitoring the research. However, records which identify your child by name or initials will be kept in a locked cabinet and will not be allowed to leave the Investigators' offices. Copies of relevant data, that identify your child only by code number, may be required by regulatory agencies. However, your child will not be identified by name, initials, or date of birth as part of this study data.

13. WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY CHILD'S PARTICIPATION?

If you have any questions or desire further information about this study before or during your child's participation, you can contact Dr. Whyte at 604-875-2711.

14. WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY CHILD'S RIGHTS AS A SUBJECT DURING THE STUDY?

If you have any concerns about your child's treatment rights as a research subject, please contact the Research Subject Information Line at the University of British Columbia Office of Research Services at 604-822-8598.

15. CONSENT TO PARTICIPATE

I have read or have had read to me all of the above. I have had enough time to consider entry to the study. All of my questions have been answered to my satisfaction. I understand that my child's participation is entirely voluntary and that he/she may refuse to participate, or I may withdraw my child from the study at any time.

The parent(s)/guardian(s) and the investigator are satisfied that the information contained in this consent form was explained to the child to the extent that he/she is able to understand it, that all questions have been answered, and that the child assents to participating in the research.

I acknowledge having received a signed and dated copy of this consent form for my own records.

Name of subject: _____

Printed name of subject's parent / Legally acceptable representative	Signature	Date
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Printed name of witness	Signature	Date
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Printed name of principal investigator/ Designated representative	Signature	Date
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