Does dexmedetomidine decrease the incidence of untoward airway events after deep or awake extubation in patients undergoing adenotonsillectomy with or without myringotomy and tube placement?

NCT #: NCT02162433

1/29/2018

MASSACHUSETTS EYE AND EAR
243 Charles Street
Boston, Massachusetts 02114

SUBJECT ID:

ORDER OF ENROLLMENT:

PROTOCOL TITLE: Does dexmedetomidine decrease the incidence of untoward airway events after deep or awake extubation in patients undergoing adenotonsillectomy with or without myringotomy and tube placement?

HSC PROTOCOL #: 14-019H

PRINCIPAL INVESTIGATOR: Makara Cayer, M.D.

Why is this research study being conducted?

You are being asked about your child taking part in a study to 1) compare two standards of care treatments at Mass Eye and Ear and, 2) determine whether an anesthesia medication that is often used in medical practice is indeed effective in lowering the risk of certain breathing complications.

You are being asked about your child taking part in this research study because your child is scheduled to have his or her adenoids and/or tonsils removed (have an Adenotonsillectomy).

This study is designed to answer two questions:

1) Which method, deep or awake, is best in lowering the risk of breathing problems during breathing tube extubation? Deep extubation is when the breathing tube is taken out while a person is still deeply under anesthesia. Awake extubation means the breathing tube is taken out while the patient is starting to come out of anesthesia but is not fully awake. We do not know which method works better. Both of these methods are commonly used in medical practice at Mass Eye and Ear.

2) Testing Dexmedetomidine to determine if it is effective in reducing breathing problems when the breathing tube is removed after Adenotonsillectomy. This medication is commonly used by anesthesiologists with children, but we do not know if it really helps. In this study, we have permission from the FDA to research this medication in our study.

   "Extubation" is the medical term used for removing a breathing tube after surgery.

Who is doing this research study and where will the study take place?

This study is sponsored by the Department of Anesthesia at Mass. Eye and Ear and has obtained permission from your surgeon to conduct this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify your child. At most, the website will include a summary of the results. You can search this website at any time.

How long will this study take and what will happen in this study?

About 336 children will take part in this research study at MEE.

This study does not involve any extra study visits. We are simply asking your permission to conduct it and to call you 24 hours after discharge to ask about your child's pain level. We are also asking your permission to access your child's surgery records for this research study.

If you allow your child to participate in this study, your child will be randomly assigned to 1 of 4 groups:
(1) Dexmedetomidine with awake extubation;
(2) Dexmedetomidine with deep extubation;
(3) Placebo (normal saline, which has no medicinal effect) with awake extubation;
(4) Placebo (normal saline, which has no medicinal effect) with deep extubation.

The assignment is random, like the flip of a coin and is done by the Pharmacist. Neither you nor the anesthesiologist will know which study medication (Dexmedetomidine or placebo) will be given at time of surgery or which method is used to remove the airway tube. The study medication will be given through a catheter that is normally inserted in your child's arm as part of your child's clinical care.

At the time of your child's discharge, we will give you a sheet to record any breathing issues. We will ask you to record the amount of pain medication you give your child. We will contact you by phone or email 24 hours following your child's surgery to ask about the pain level, pain medication used, and whether your child has any nausea, vomiting, or respiratory complications.

What are the risks and possible discomforts from being in this research study?

Dexmedetomidine may cause bradycardia (slow heart rate) and hypotension (low blood pressure), which are easily treatable. These complications normally occur in 10-20% of pediatric cases.
The awake method of airway removal may cause some bleeding and coughing. The deep method, may cause laryngospasm (temporary cramp in the larynx). Both anesthesiologists and nurses in charge of your child will be closely monitoring as part of standard of care and know how to handle these routine complications

What are the possible benefits from being in this research study?

Your child may or may not receive any direct benefit from taking part in this study. However future children may benefit from determining which method and anesthesia work best.

What are the alternatives to taking part in this study?

Your child will undergo deep or awake extubation, whether or not you agree to take part in this research study. Your child may or may not receive Dexmedetomidine per discretion of the anesthesiologist in charge. Your alternative is to not participate.

Can I decide to stop taking part in this study?

Your child's participation in this research study is entirely voluntary, and you may withdraw your permission even after signing this consent. The quality of care your child will receive at the Massachusetts Eye and Ear, the payment for your child's health care, and your child's health care benefits will not be affected if you decide not to participate or if you withdraw your child from the study.

To withdraw from the study, you can inform a member of the research team at any time and tell them that you no longer want your child to take part.

Your child doctors may also choose to withdraw your child from the research:

- If the anesthesiologist determines that the research assigned extubation method should not be used clinically;
- If the surgeon or anesthesiologist determines that it is clinically in the best interest for your child not to have the study medications at time of surgery;
- If there are complications such as low heart rate and lowe blood pressure.

Will I receive payment for taking part in this study?

You will not receive a payment for allowing your child to participate in this study.

What will I have to pay for if I take part in this research study?

There are no additional costs for participation. You will still be responsible for any co-pays required by your child's insurance company for standard treatment.

What happens if I am injured as result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for the injury aside from what was described above. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the researcher in charge of the study as soon as possible. The researcher's name and phone number are listed on this consent form.

Contact information if you have questions or concerns about this study

You are free to ask any questions you may have regarding the study or about your child's rights and treatment as a research subject. Further information about any aspect of this study is available now or at any time during the course of the study from the study coordinator, Alex Ciaramella at 617-573-4016 or the principal investigator, Dr. Makara Cayer at 617-573-3380.

Additionally, you may contact the Office of Research and Academic Affairs, at (617) 573-3446 if you have any questions or concerns about your child's rights and treatment as a research subject.

If I take part in this research study, how will you protect my confidentiality?

We cannot guarantee total confidentiality. However, we will code your data so that we will not directly link information that identifies to your data. We will use a study code and keep the link between your identifiers and the code in a separate, password-protected file. We will keep all data in a locked area and allow access only to study staff.

We may publish the results of this research study in a medical book or journal or use the results to teach others. However, we will not use your name and other identifying information for these purposes without your specific authorization.

If I take part in this research study, how will you protect my privacy?

During this research, we will collect identifiable information about your health. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. All health care providers subject to the Health Insurance Portability and Accountability Act (HIPAA) are required to protect the privacy of your information. The research staff

at the MEE is required to comply with HIPAA and to ensure the privacy of your information. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

Past, present, and future medical records
Research procedures, research office visits, tests, interviews and questionnaires

What is the purpose of collecting, using, and sharing of your protected health information?

We are asking you to take part in the research study described in this research consent form. In order for you to participate, we need to be able to collect, use and share your protected health information.

If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name, date of birth, phone number, and medical record number.

Who may see, use, and share your identifiable health information and why they may need to do so

- MEE research staff involved in this study
- The sponsor(s) of study drug/device, and the people or groups it hires to help perform this research
- Other researchers, health care providers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within MEE who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The MEE ethics board that oversees the research and the MEE research quality improvement programs
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other U.S. or foreign government bodies that oversee or review research)
- Public health and safety authorities (For example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)

We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy. However, once we share your information outside of MEE, we cannot promise that it will remain private. Some of the individuals or agencies listed above may not have to follow the same privacy and security rules that we follow and therefore may not be required to provide the same type of confidentiality protection.

Because research is an ongoing process, we cannot give you an exact date when we will destroy or stop using or sharing your health information. We will collect, use, and share your health information until the end of this research study, which may be after your direct participation in the research project ends.

Your privacy rights:

You have the right not to sign the form that allows us to use and share your health information for research; however, if you do not sign it, you cannot take part in this research study. You have the right to take away your permission for us to use and share your health information for this research study at any time. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once you withdraw your permission, you cannot continue to take part in this study.

When you withdraw your permission, we will not gather new health information that identifies you after that date. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that we used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. For some studies, you may only get such information after the research is finished.
Statement of the Person Giving Informed Consent and Authorization

- I have read this consent form
- This research study has been explained to me, including the risk and possible benefits (if any), other possible treatments or procedures, and other important parts of the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.
- I will be given a signed copy of this form to keep.

Signature of Parent(s)/Guardian for Child

I give my permission for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

_____	_____	_____
Parent(s)/Guardian for Child	Date	Time

_____
Print Name

Child Assent (children 14 to 16)

Statement of Child Giving Assent

- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important parts of this study.
- I have had the opportunity to ask questions, and my questions have been answered.

I agree to take part in this research study and agree to allow my health information to be used as shared as described above.

_____	_____	_____
Child, Ages 14-16	Date	Time

Signature of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

_____	_____	_____
Study Doctor or Person Obtaining Consent	Date	Time