Title: The Articulated Oral Airway as an Aid to Mask Ventilation, a Prospective Interventional, Non-Inferiority Study

NCT# 03144089

Ron Abrons, MD

May 16, 2021

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INFORMED CONSENT DOCUMENT

Project Title: **The Articulated Oral Airway as an Aid to Mask Ventilation, a Prospective Interventional, Non-Inferiority Study**

Principal Investigator: Ron Abrons, M.D.

Research Team Contact: Ron Abrons, M.D [redacted]

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you have decided that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you will be undergoing asleep mask ventilation (breathing for you while asleep prior to placement of a breathing tube) for your elective surgery.

The purpose of this research study is to compare two different devices used to help breathe for you prior to placement of the breathing tube. We will determine if mask ventilation is easier with a new device, the Articulated Oral Airway, than with a commonly used device, the Guedel oral airway. We will also evaluate whether one device will result in less trauma (bleeding, sore throat) for you than another. The Guedel oral airway is placed, after you are asleep, into your mouth and acts as a tunnel for oxygen to pass through. The Articulated oral airway is placed in to same manner, but its shape can be changed slightly after placement. The Articulating oral airway has been cleared for use by the US Food and Drug Administration (FDA) but has yet to be formally studied.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 58 people will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last until you are seen in the recovery room after surgery. Participation should not affect the actual surgery time or length of stay in the hospital.

WHAT WILL HAPPEN DURING THIS STUDY?

If you agree to participate, we will obtain and use the information from your health record for your height, weight, age, sex, clinical diagnoses and type of surgery.

On the day of surgery, you will come to the Day of Surgery Admission (DOSA) or Ambulatory Surgery Center (ASC) preoperative area and be prepared for surgery in the same way as if you were not in the study. No additional preparations are needed for this study. The anesthesia and surgical procedures will be discussed with you by your anesthesia and surgical team members and your questions will be answered.

After you are completely asleep, both oral airways will be placed and evaluated, one at a time and in random order. This means that both oral airways will be placed, but which one is placed first or second is determined purely by chance, like flipping a coin. You will have a 50/50 chance of receiving either oral airway first.

The actual study procedure will begin when you arrive in the operating room. Numbers which reflect how easy it is to breath for you through each oral airway will be collected via a video of the anesthesia monitor. There will never be any pictures or videos of you, just the anesthesia monitor. The study will end 15-45 minutes after your surgery when a member of the research team will visit you in the recovery room, ask you if you are having any sore throat, and take a look in your mouth. If mask ventilation is not successful with either device, the anesthesia team will switch to an alternative method of breathing for you of their discretion.

Oral airways are commonly used for patients who are eligible for this study but are not needed for everyone. This means that if you are not in the study you may not have an oral airway placed at all and if you are in the study, you will definitely have both placed, one after another, as discussed above.

Additionally, after surgery, we will review your medical record to check for any complications which might have been related to airway management.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Guedel oral airways were invented in 1933 and are commonly used at UIHC. Articulated Oral Airways are a new device which have only recently gone into use and have only been tested at UIHC. The placement of any device in the airway (oral airways, breathing tubes, etc) carries the risk of injury to tissue. This risk may be increased with two oral airways being sequentially placed as opposed to one or zero being placed. There are no known additional financial, physical, or legal risks to you. This said, the Articulated Oral Airway has yet to be formally studied so we cannot say for sure if it involves identical, more or less risk than a Guedel oral airway.

There is a risk of loss of confidentiality. Measures in place to protect confidentiality are indicated in the 'What About Confidentiality' section later in this document.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study. However, we hope that in the future, other people might benefit from this study because the information gathered may be used to determine which oral airway best aids mask ventilation.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could receive the same procedure without being in the study with the anesthesiologist deciding which oral airway, if any, will be used.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study. You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

This research is partially funded by grants from the University of Iowa Research Foundation, who owns the patent on the Articulated Oral Airway. The University and the research team are receiving no payments from any other agencies, organizations, or companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will assign you a study number and all data collected on you will only be associated with that study number. We will keep all information from this study in locked offices and on password protected computer files. Any paper copies will be kept in a locked file cabinet within a locked office. The consent you sign will not be kept with the paper copy of data so that no one can identify who the data belongs to. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The University of Iowa Hospitals and Clinics generally requires that we document your participation in research occurring in a University of Iowa Health Care facility. This documentation will be in either your medical record or a database maintained on behalf of the institution reflecting that you are participating in this study. The information included will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

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 you. At most, the website will include a summary of the results. You can search this website at any time.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires your health care provider to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study and for your treatment. Once your health care provider has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research related. Your signature on this Consent Document authorizes your health care provider to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us

to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Dr. Ron Abrons, [redacted] However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Ron Abrons [redacted]. If you experience a research-related injury, please contact: Dr. Ron Abrons [redacted].

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://research.uiowa.edu/hso. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

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Subject's Name (printed): _____

Do not sign this form if today's date is on or after $STAMP_EXP_DT.

_____ _____
(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)