Cover Page for the protocol

Official Title:	Novel Airway Device to Aid Endotracheal Intubations
NCT number:	NCT03340207
Document Type:	Study Protocol including Statistical Analysis Plan incorporated in the protocol and Informed Consent
Date of the Document:	April 15 2019 for the study protocol; The latest version of the informed consent template was April 02, 2015

1. Introduction/Objective

The proposed study will examine the efficacy of Pneumoglide on facilitating the process of endotracheal intubation while it prevents injury to the upper teeth and aspiration of gastric contents into the lungs. These two complications are among common mishaps during endotracheal intubation by less experienced operators.

2. Subjects/Methods/Data Collection

This study will be a prospective clinical trial of patients who will receive general anesthesia with endotracheal intubation for their surgery. All patients undergoing general anesthesia and assigned to be anesthetized by an anesthesia team that includes a PGY-2 or PGY-3 residents will be screened for enrollment. All patients with recognized as difficult intubation or with obvious anatomical deviation of their airway (congenital or cancer-related) will be excluded. After initial screening and signing an informed consent, patients will be randomized into two groups: Group I will be intubated with while Pneumoglide device is used and Group II will be intubated in a conventional method without using Pneumoglide device. The primary endpoint of the study will be the success of the intubation by the trainees, The secondary outcome variables will include the number of the attempts to intubate the trachea, the time it lapse from the reaching to the laryngoscope device until the time the trachea is intubated and the correct placement of the endotracheal tube is verified. Additionally, we will collect all cases the required assistance from the attending staff in either group. Among patients in group I, the grade of vocal cord visualization will be documented with direct laryngoscopy with Macintosh blade 3-4 before inserting Pneumoglide and after insertion of the device. In group II, this variable will not be collected. Collected data will soon be entered into an Excel worksheet and will be saved in an approved Share Point folder allocated to this project. A copy of the informed consent and HIPPA waiver will also be saved in this folder. Access to this folder is granted for the authorized personnel and for the Ethics officer for auditing purposes.

3. Data Analysis

There is currently no available data with the use of this device, therefore, we were unable to do a power analysis for sample size determination. This study is therefore considered a pilot project and the results obtained form this study can be used for sample size determination in future clinical trials.

Data will be analyzed quantitatively using VA approved programs, located at Dr. N. Nader's office. Following removal of patients' identifiable information except for age and the date of procedure, the data will be transferred to an SPSS worksheet that is installed on a MacBook Pro located at Dr. Nader's Office (204C) for further statistical analysis. The output files of the analyses will then reloaded to the Share Point folder and will remain there for future access by the authorized study team members.

4. Risks

This project will only offer minimal risk to patients directly related to the use of Pneumoglide device This devices is classified as Class I by FDA which only granted for devices that has minimal risk to patients, and therefore was exempted from obtaining IND number from FDA. The only risk is from possible injuries to lip, teeth and oral mucosa from rough handling of the airway which basically same to patients from either group. Additionally, there may be some difficulty in intubating trachea by novice trainees. All these procedures are performed in the presence and direct supervision by an attending

anesthesiologist with expertise in placing endotracheal tubes. Patient safety is the highest priority and all attending are trained to intervene timely and decrease any potential mishap from occurring.

5. Benefits

This study will benefit both future patients of the VA as follow:

a. Facilitating intubation by improving visualization of the airway (glottis)
b. Decrease the risk of injury to the teeth, lips and oral mucosa by adding another protective layer
c. Decrease the risk of gastric aspiration by occluding the esophageal opening while placing the endotracheal tube.

Data Collection tool (Excel Worksheet)

Name	Date	Group	Age	MP	preLG	PostLG	Success	#Att	TTI	FHelp	EsoInt	Inj	GasAsp
Case1													

Variable information:

Name: (Name+Last4)

Date: mm-dd-yy

Group: Device group

Age: years

MP: Mallampathi Classification of the airway

PreLG: Laryngeal grade before insertion of Pneumoglide

PostLG: Laryngeal grade after insertion of Pneumoglide

Success: Successful intubation by the trainee

#Att: Number of the attempts to successfully intubate

TTI: Time to intubate (minutes)

FHelp: Help from the faculty staff

Esoint: Inadvertent esophageal intubation

Inj: Injury to the lips, teeth and oral mucosa

GasAsp: Gastric Aspiration

Research Informed Consent Document

Department of Veterans Affairs
VA Western New York Healthcare System, Buffalo, New York

PARTICIPANT NAME:	**DATE:**
PRINCIPAL INVESTIGATOR:	*Nader D. Nader, MD PhD*
TITLE OF RESEARCH STUDY:	*Clinical Trial of PneumaGlide: A Novel Airway Device to Aid Endotracheal Intubations for Novice Intubators*

BLACK FONT: **The black font throughout the template is required language.**
RED FONT: **The red font requires you to input language specific to your study, or provides instructions for the section.**
BLUE FONT: **The blue font throughout the template is optional, and only required if necessary for your study.**

Informed Consent to Participate in Research

Sponsor: UB Center for Advanced Biomedical and Bioengineering Technology (UB CAT)

The investigators have been approved to complete this study by the Facility Financial Conflict of Interest Administrator.

We are asking you to volunteer for a research study at the VA Western New York Healthcare System [VAWNYHS].

The purpose of this study is *to examine the feasibility of using Pneumoglide as an aid to place the endotracheal tube by the novice trainees in a supervised clinical setting*.

Should you take part in this study?

This form tells you about this research study. This form explains:

- Why this study is being done.
- What will happen during this study and what you will need to do?
- Whether there is any chance you might experience potential benefits from being in the study.
- The risks of having problems because you are in this study.

Before you decide:

- Read this form.

IRB Approval Stamp

Research Informed Consent Document
Department of Veterans Affairs
VA Western New York Healthcare System, Buffalo, New York

PRINCIPAL INVESTIGATOR: *Nader D. Nader MD, PhD*

TITLE OF RESEARCH STUDY: *Clinical Trial of PneumaGlide: A Novel Airway Device to Aid Endotracheal Intubations for Novice Intubators*

- Have a friend or family member read it.
- Talk about this study with the person in charge of the study or the person explaining the study. You can have someone with you when you talk about the study.
- Talk it over with someone you trust.
- You may have questions this form does not answer. You do not have to guess at things you don't understand. If you have questions ask the person in charge of the study or study staff as you go along. Ask them to explain things in a way you can understand.
- Take your time to think about it.

It is up to you. If you choose to take part in this study, you will need to sign this consent form. If you **do not** want to take part in this study, you should **not** sign the form.

Are you in any other research studies? ____Yes ____No

Why is this research being done?

We are asking you to participate in this study because you are scheduled to undergo a procedure that requires general anesthesia. General anesthesia refers to state of sleep during which you will not have any recollection of events, perception of pain or movement during the course of surgery/procedure. Because of induced paralysis of muscles, it is critical to maintain respiration through artificial breathing. Placement of tube into the windpipe is a necessary step for maintaining mechanical ventilation. Under direct supervision of the anesthesiologists, the trainees place endotracheal tube with video assisted visualization of the windpipe. This device (Pneumoglide) is designed to improve the visualization of the windpipe. The quality of view and the time it takes from the start until successful placement of the tube into the windpipe will be measured and recorded for comparison.

How long will you be in the study?

You will be in the study for *duration of general anesthesia in the operating room* and make *no further follow up* visits. *However, you will be asked to complete a short survey about the possible presence of sore throat or any breathing issues within 72 hours of discharge from the hospital.*

What will be done if you agree to be in this study?

You will be asked about your willingness to participate in this project on the day that you are being evaluated for your fitness for anesthesia. If you agree to be in this study, you will be randomly assigned to either a group in whom this device will be used for placement of a tube into your windpipe or placement of the tube will take place without utilizing the study device. The study device is a conical device that is designed to obstruct the opening of all orifices in your mouth other than the windpipe. That is why it is proposed that this device may decrease the likelihood of food spillage into your lungs. Additionally, this device is proposed to bring the opening of the windpipe to the front and facilitate placement of the tube into your windpipe. The quality of visualization is graded (as per the published

standards) before placement and after placement of the device and recorded. A member of the study team will time the process of tube placement from the time of inserting video scope into your mouth until the time that the breathing tube is successfully placed into the windpipe. This information will be compared to those patients in whom no such a device is placed (controls). You will have a 50% chance to be assigned to the device group or the control group. This random assignment is like flipping a coin; you will have a one in two chance of being assigned to either group.

How many other people will be in this study?

About *200* people will be in this study at this location. People will also participate at other study sites. A total of about *400* people will be included all together.

What are the possible risks?

This device is made out of soft rubber material and therefore the risk of injuring the mucosa of your mouth, teeth, crowns or dentures is minimal. During certain stages of anesthesia, especially during emergence when the muscle paralysis is reversed, some patient will develop some degree of clenching the teeth that may cut through this device. If this occurs, the remaining of the device will be carefully removed from the mouth before removing the tube from your windpipe.

What are the possible benefits to you or to others if you are in this study?

You may or may not be helped by being in this study. However, by participating in the study, you may help us learn how to benefit patients in the future.

Will it cost me anything to be in this study?

None of the participants will pay for the cost of *this airway device* because they are only for research study purposes. You would receive the following *general anesthesia with placement of tube into your windpipe* even if you were not in the study because they are part of the standard care for your condition.

Will you be paid for taking part in this study?

You will be compensated for participation in this study project for the amount of $10.00, which will be paid upon the receipt of your close out survey (consisting of 2 questions). This short survey the will be handed to you upon discharge from the hospital along with self-addressed and paid postage envelopes. An Internal Revenue Service (IRS) Form 1099 may be generated, which will use your Social Security Number.

Does pregnancy prevent me from participating in this study?

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Since during pregnancy the tone of the throat muscles and the volume of the stomach contents are increased, pregnant women are at increased risk of food spillage into the lungs and therefore you should not participate in this study if you are pregnant. You must inform the study staff right away if you or your partner becomes pregnant.

What happens if you decide NOT to take part in this study?

You should only be in this study if you want to volunteer. You do not need to be in the study to please the study doctor or the research staff.

If you decide NOT to take part:

- You will not be in trouble or lose any rights you normally have.
- You will still have the same services you would normally have.
- You can still get your regular medical care from your regular health care practitioner.

You will still receive general anesthesia for your procedure and the trainees in Anesthesiology under direct supervision by a licensed Anesthesiologist will place a tube into your windpipe using standard methods.

What if you join the study and decide you want to stop later on?

You can decide after signing this informed consent document that you no longer want to be in this study. **We will tell you about any new developments, which might affect your willingness to continue to participate in the study.** However, you can decide you want to stop taking part in the study for any reason, at any time. If you decide you want to stop being in the study, tell the study staff as soon as you can.

- We will tell you how to stop safely. We will tell you if there are any dangers if you stop suddenly.
- If you decide to stop, you can continue getting care from your regular health care practitioner.

Are there reasons we might take you out of the study later on?

Even if you want to stay in the study, there may be reasons we will need to take you out of it. You may be taken out of this study if:

- We find out it is not safe for you to stay in the study. For example, your health may worsen.
- You are not coming for your study visits when scheduled or completing study tasks as needed.
- The funding for the study is stopped.

What if you are injured while you are on the study?

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The VA Western New York Healthcare System will provide necessary medical treatment to you if you are injured by being in a research study. This does not apply to treatment for injuries that occur because you did not follow study procedures. Except in limited circumstances, the necessary care will be provided in VA medical facilities. Any expenses not covered by your insurance may be covered by the VA, consistent with applicable law, regulation, and policy.

Privacy and Confidentiality

Any information obtained about you in this study will be treated as confidential and will be stored as stated in the Privacy Act of 1974. In order to follow federal regulations, records identifying you may be inspected by sponsors of this study and others including, but not limited to:

- **The VAWNYHS Medical Center Research and Development Committee and its Subcommittees**
- **VAWNYHS Research Staff and Research Compliance Officer**
- **The Office for Human Research Protections (OHRP)**
- **VA Office of Research Oversight (ORO)**
- **Office of the Inspector General (OIG)**

How will your information be used?
The ways your study doctor will use your study-related health information and the people who may receive it are identified in a separate form entitled, "Department of Veterans Affairs HIPAA Authorization for Release of Protected Health Information for Research Purposes". You will be asked to sign that form to show that you give permission for these uses and sharing of your information. You do not have to sign the authorization form. However, if you do not sign, you will not be able to participate in the study.

How will your information be stored?
All relevant clinical information will be collect on paper and transferred to an Excel-based datasheet, which will be stored in a password protected SharePoint folder. This folder will only be accessed by authorized study team members.

How will your information be sent to the sponsor?
Clinical source documents will not be transmitted to the sponsor. Only data after they are analyzed and tabulated will be transmitted to the sponsor and will certainly not include any identifiable information.

How will your information be kept or destroyed?
Your research records will be retained in accordance with the Veterans Health Administration (VHA) Records Control Schedule.

How will your information be described to others?

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We may publish what we learn from this study. If we do, we will not let anyone know your name. We will not publish anything else that would let people know who you are.

This device is classified as Class I and therefore it was exempted from obtaining a FDA-IND number.

How do you withdraw permission to use your information?

You can revoke this form at any time. This means you can tell the research team to stop using and sharing your information. If you revoke this form:

- **You will no longer be a participant in this research study.**
- **We will stop collecting information about you.**
- **The information that we have collected before you tell us to stop may already have been used or shared, or we may need it to complete the research, so you cannot withdraw that information.**
- **Staff may follow-up with you if there is a medical reason to do so.**

To revoke this form, you must tell us in writing. To revoke your authorization, you must write to the Release of Information Office at this facility, or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study.

If you revoke this authorization, your research doctor or staff can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Your Rights:

You can refuse to sign this form. If you do not sign this form:

- You will not be able to be in this research. However, you can receive other procedures that are currently available for your condition as part of your regular medical treatment.
- This will not change your health care outside of this study.
- This will not change your health care benefits.
- This will not change the costs of your health care.

There will be no costs to you for any treatment or testing done as part of this study.

Eligibility for medical care is based on the usual VA eligibility policy. It is not guaranteed by being in a study. If you get medical care by the VA that is not part of the study, you may be charged co-pay for that medical care based on your VA eligibility.

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You can get answers to your questions, concerns, complaints or issues about this study.

NADER D. NADER, MD, or *his* designee, has explained the study to you and answered all of your questions. If you have questions, concerns or complaints about the research, you have been told you can call *Dr. Nader* at *716-341-2715* during the day and *Dr. Nader* at *716-341-2715* after hours. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. If you have questions about your rights as a research participant, or if you think you have a research-related injury, you may contact the Chair of the Research & Development Committee at (716) 862-6528 or the Patient Advocate at (716) 862-8752. You may also contact the Research Compliance Officer at (716) 862-3218 if you have concerns, questions, or complaints and cannot reach the research team, or if you wish to talk to someone else.

You have been told that if you receive care from non-VA providers, you should tell your other healthcare providers about your participation in this study. If your provider knows of information that may be useful to this study, you will tell them to contact the Principal Investigator (PI).

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Statement of Participation in Research:

You have read or have had read to you all of the above. It is up to you to decide whether you want to take part in this study. If you want to take part, please read the statements below and sign the form if the statements are true.

I freely give my consent to take part in this study and authorize that my health information, as agreed above, be collected and disclosed in this study. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

I understand that I do not have to be in this study. My refusal to take part will involve no penalty or loss of rights to which I am entitled. I may leave this study whenever I wish without penalty or loss of VA or other benefits to which I am entitled.

_____
Participant's Signature

_____ _____
Printed Name of Participant Date

_____ _____
Signature of Individual Obtaining Participant's Consent Date

_____
Printed Name of Individual Obtaining Participant's Consent

_____ _____ _____
Surrogate/Legal Representative Signature (Print Name) Date

_____
Relationship to Participant