A comparison of positional stability: EZ-blocker versus Left Sided Double Lumen Tube
in adult patients for thoracic surgery

Informed Consent Form to Participate in Research
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INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have been scheduled for surgery on your chest that requires the anesthesiologist to perform lung isolation, which means breathing for you using only one lung during the surgery. We are studying two different devices used to accomplish this. One of these devices is called a "bronchial blocker" specifically the "EZ-blocker" bronchial blocker and the other device called a "double lumen tube." These devices allow the anesthesiologist to have you breathe with only one lung while you are asleep for the surgery. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to determine if there any differences between the EZ-blocker and a double lumen tube in terms of both devices staying in the correct position during surgery while breathing with one lung. Both of the devices being analyzed in this study have already been approved by the Food and Drug Administration (FDA) for medical use. In this study there are no experimental devices or procedures being used, you will receive the standard of care for your surgery.

. In this study we will be comparing the EZ blocker and a double lumen tube in order to determine if there are any significant differences in terms of getting a sore throat or other voice box or windpipe injuries associated with one device or the other. There is at least one study which would seem to say that the devices being compared in this study are equal in terms of staying position, but that there may be an increase in throat discomfort or windpipe injuries associated with double lumen tubes because of their size. Double lumen tubes have been in use for many years in chest surgery and the EZ-blocker has been used for 6 years now and both are considered very safe.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

At least 160 people at this hospital having this type of surgery at Wake Forest Baptist Health will take part in this study. As many as 200 people may participate.

WHAT IS INVOLVED IN THE STUDY?

If you choose to participate in this study there are no extra visits required for the study. You will arrive for your surgery at the time that you have been instructed. A study representative will talk to you on the day of surgery to make sure you have not changed your mind about participating and will answer any other questions about the study you may have thought of since agreeing to participate at your preoperative assessment visit. Nothing else will be required from you prior to surgery and your procedure will be done the same way it would be done if you were not enrolled in the study. After your surgery we will check on you the next day and then again two days after your surgery to ask you a couple of questions about how you are feeling and have you make a mark on line to indicate how your throat is feeling. If you are not in the hospital, we will call you on the telephone and ask you about your throat.

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an *equal* chance of being placed in one of the two study groups.

On the day of surgery you will come to the preoperative holding area where a nurse will greet you and ask you a standard set of questions that he or she asks all surgery patients and she will start an IV. A study representative will speak to you and make sure you have not changed your mind about participating in the study. At this point, we look to see which group you have been randomly assigned to. You will not be told which group you have been assigned to. When you are ready and all safety checks have been performed, you will be taken to the operating room. You will be placed on the operating room table and the anesthesiologist will give you medications to sleep.
The following procedures would be dependent on which study group you have been assigned to:

Participants assigned into Group I
In Group 1, an anesthesiologist will place a specialized breathing tube with two channels for air flow which goes through your vocal cords and voice box into your windpipe. Once the breathing tube is in place the anesthesiologist will make sure it is in the correct place using a flexible fiberoptic bronchoscope. A flexible fiberoptic bronchoscope is a thin noodle-like tool that can be steered through the breathing tube to allow the anesthesiologist to look at the breathing tube position in your lungs. During the surgery the anesthesiologist will clamp one of the two breathing channels so that you are only breathing with one lung during the surgery.

Participants assigned to Group II
In Group II, once you are asleep we will use a "laryngoscope" to place a normal breathing tube. A laryngoscope is an instrument used to look at the larynx for inserting a tube through it. Once the laryngoscope is in place, a device called an EZ-blocker will be placed either through the breathing tube into the windpipe. At this point, the anesthesiologist will make sure the breathing tube is in the correct place. The anesthesiologist will use a flexible fiberoptic bronchoscope to look down the breathing tube to position the EZ-blocker into the correct place. If it is not correctly placed, the anesthesiologist will adjust the EZ-blocker to move it to the correct position for your surgery by moving it backwards and forwards sometimes with a twisting motion. After

it is in the correct position, the anesthesiologist will inflate the balloon at the end of the blocker on the side of surgery. The anesthesiologist will then check to see if you are breathing on only one lung like you need to during the surgery. You will then be moved on to your side for the surgery. Prior to beginning the surgery the anesthesiologist will check one more time to make sure the EZ-blocker did not move out of position and will adjust it if necessary.

We will record how much time it takes to place the double lumen tube or the EZ-blocker from the time that you go to sleep to the time that the device is correctly placed.

The surgeon will then perform the surgery. If the EZ-blocker or double lumen tube moves during the surgery, we may have to adjust the position of the device in order to make sure you are only breathing on the lung. We will record the time and number of repositionings.

Once the EZ-blocker is no longer necessary at the end of the surgery, the balloon at the end of the EZ-blocker will be deflated and the EZ-blocker will be removed prior to you waking up.

At the very end of the surgery your anesthesiologist will turn off the anesthesia and wake you up. Just prior to waking up in the operating room the standard breathing tube or double lumen tube will be removed. You will be taken to the recovery room like all patients who have had surgery.

You will be admitted to the hospital and we will check on you on the first day after surgery and the second day after surgery to ask you how you are feeling. After that your participation in the study will end and we will not collect any more information about you for the study.
If you take part in this study, you will have no additional tests or procedures beyond what you would have if you did not participate in this study. However, we will randomize you to either EZ-blocker or double lumen tube instead of allowing the physician to choose.

As part of this research study, you may be photographed or videotaped while under anesthesia. This is being done for educational purposes to explain and better describe to other anesthesiologists the details of both these techniques. You can also withdraw your consent to use and disclose the photograph or videotape before it is used. You should also understand that you will not be able to inspect, review, or approve the photographs, or videos or other media (including articles containing such) before they are used in this study. No identifying information will be presented with the video or pictures.

Please choose one of the following regarding the use and disclosure of the photograph/videotape/ used in this research study:

_____ I would like the photographs/videotapes of me to be destroyed once their use in this study is finished.

____ The photographs/videotapes of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review, or approve their future use.

How Long Will I Be in the Study?

You will be in the study from the day you have your surgery until 2 days after the surgery. There is no long term follow-up related to this study.

You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff. In this study there are no potential health or safety issues from withdrawing from the study.

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the EZ-blocker will be the same whether you are in the study or not. . During the placement of a breathing tube or the EZ-blocker there is a risk of damage to the vocal cords, the throat, and the windpipe. This study is comparing two FDA approved methods for performing lung isolation. You will be randomly assigned to one of the two groups. It is possible that one group may have a better response than the other. Therefore, there is a risk that you may be assigned to a group that does not perform as well as its comparison.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Pregnant women are excluded from participation in this study. Because some methods of birth control are not 100% reliable, a pregnancy test is required at least 10 days from your last normal menstrual period, if you are a sexually active woman of childbearing potential.

Are There Benefits to Taking Part in the Study?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

What Other Choices Are There?

You do not have to be in this study to get surgery. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options:

- You will still receive surgery and it will still be necessary in most cases to breathe on one

lung during this operation while you are under anesthesia.

- The anesthesiologist will decide what best way to do this in your case: either with a EZ-blocker or a double lumen tube.
- A double lumen tube is a commonly used, larger breathing tube placed in patients to allow for breathing on one lung during chest operations.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:**

Age
Weight and BMI
Gender
General Medical History
Previous Surgeries
Past/Current Medical problems
Radiology exams (such as CT scans) taken prior to your procedure
ASA (aspirin) status
Type and side of surgery
Duration of one lung ventilation
Duration of the surgery and anesthesia
We will collect data on device placements and device repositioning (if applicable)
Whether or not you have a sore throat after the surgery

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services

(DHHS) and similar agencies in other countries.

Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research or are providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest Baptist Hospital

2) Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws

3) Representatives from government agencies such as the US Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS) and other U.S. or foreign government bodies, if required by law or involved in overseeing the research. Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups, it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire and any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Ben Morris M.D. that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Ben Morris, MD
[redacted]

[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record.

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 Web site at any time.

WHAT ARE THE COSTS?

There are no costs to you for taking part in this study. All study costs such as data gathering, data storage and record keeping will be paid for by the study. Costs for your regular medical care, anesthesia and surgery, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00038220
Meeting Date Approved 9/24/2019
Version Valid Until: 9/23/2020

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest University Health Sciences. This sponsor is providing money and support to help conduct this study. The researchers do not, however, hold a direct financial interest in the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted]

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries, or to report a study related illness, adverse event, or injury you should call Ben Morris, MD or Wes Templeton, MD at [redacted] or [redacted] (after hours).

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, new information becomes available, or because the entire study has been stopped.

You will be given any new information if we become aware of anything that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study

investigator Ben Morris, MD or Wes Templeton, MD at [redacted] or [redacted] (after hours).

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm