

Approved on:	03/26/2019
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Study number:	BH-19-006

Baystate Health

RESEARCH CONSENT FORM

Title of Project:

PHASE II STUDY: Feasibility of providing Volume Targeted Ventilation in the Delivery Room

MAIN STUDY: Feasibility and Impact of Volume Targeted Ventilation for preterm infants born < 32 weeks gestational age with need for invasive Positive Pressure Ventilation in the Delivery Room in reducing neonatal pulmonary morbidities

Study Sponsor: Department of Pediatrics

Principal Investigator: Ruben Vaidya, MD

Study Participant: _____

If you are a parent or guardian of a child under 18 years old or the legal representative of an adult, the word “you and your” in this form refers to the child who will be in the study.

WHY ARE YOU BEING ASKED TO TAKE PART IN THIS RESEARCH?

We are talking to you about this research study because you were born prematurely before 32 weeks of gestation.

This form gives you important information. Please read it carefully and ask questions before you make a decision. Ask your study doctor or the study team to explain any words or information in this form that you do not understand. You may want to talk about this study with your family, your friends, and your other health care providers. Please take your time. You should not sign this form until all of your questions are answered.

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care, any legal rights, or any benefits that you are otherwise entitled to.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of this research study is to understand the best way to provide respiratory or breathing support to a preterm infant who requires endotracheal intubation (breathing tube placement) in the delivery room. Currently, when babies have a breathing tube placed in the delivery room, we give them a specific pressure with each breath. Depending on the baby's lungs condition, this pressure gives different volume for each breath, which may be too large or too small. We are trying to evaluate if it would cause less trauma to the baby's lungs to give a specific volume rather than a specific pressure for each breath. In Phase I of this study we have already shown the ability of measuring this support. We are asking you to participate in Phase II of this study, where we are trying to adjust the volume of breaths given such that they are in the range needed specifically by your weight. The goal is to prevent lung injury by giving the appropriate breath volumes after intubation in the delivery room.

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

HOW IS THIS RESEARCH STUDY BEING FUNDED?

This research study is being funded by Baystate Medical Center, Department of Pediatrics and is funded by Research Pilot Award program (RPAP) Grant, provided by Baystate Office of Research. Dr. Vaidya is supported by the RPAP Grant, but is not paid additionally for undertaking this study by any other sources.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

This research is being conducted only at Baystate Medical Center. We expect to enroll 30 patients in Phase II of the study.

HOW LONG WILL YOU BE IN THIS STUDY?

You will receive the study intervention during the first 48 hours of life, but our research team will follow your progress till you are discharged from the hospital. No additional intervention or monitoring will be performed after the first 48hours, and we will only collect outcomes data from your electronic medical record from there on. You will not need additional study related follow up after NICU discharge.

CAN I STOP TAKING PART IN THIS STUDY?

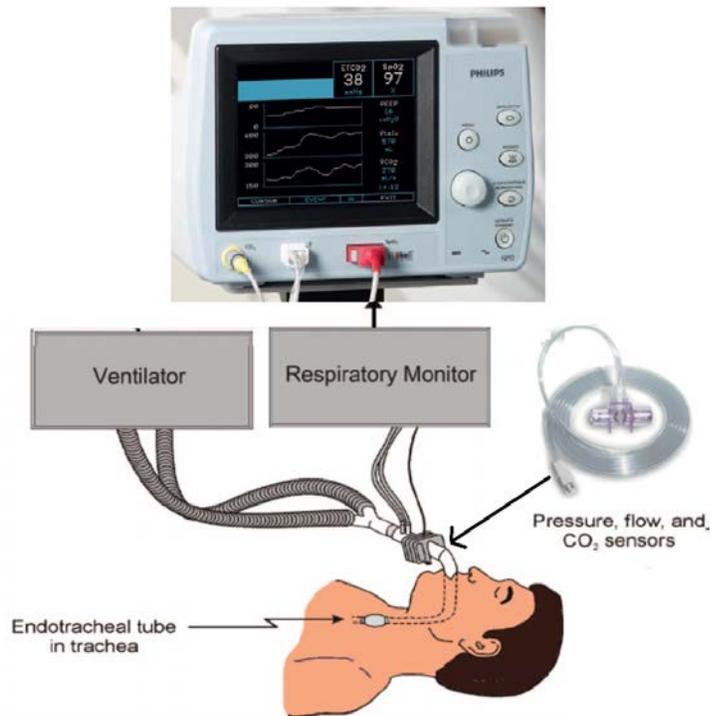
Yes, you can tell the study doctor if you have decided to or are thinking about leaving the study. The study team may ask your permission to continue to contact you or follow your medical information to see how you are doing. Information that has already been collected about you will remain part of this study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If the study is stopped by the sponsor

WHAT WILL HAPPEN IN THIS STUDY?

If found eligible for the study a small “flow sensor device” will be attached in between the breathing tube and the ventilator tubing. This device will be connected to a respiratory monitor (Philips Respironics NM3 device), an FDA approved device, which will measure the volume of each breath given (tidal volume). At present we do not routinely use this device in the delivery room, but for this study, we will use this device in all patients enrolled in the study to measure the volume of the breaths provided. . In the first phase of the study, we have established that we can measure the volume of each breath with this flow sensor device. In the current phase of the study you will be randomly assigned to one of the study group as mentioned below.



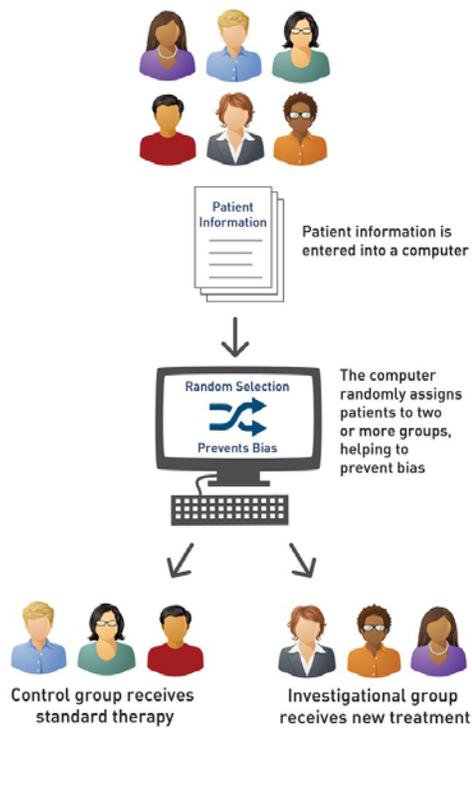
Random Assignment:

If you are eligible for this study, you will be placed into one of the study groups by chance (like flipping a coin). You will have an equal chance of being placed in any one of the study groups. Infants in both groups will have a “flow sensor device” with the Philips Respirator NM3 device, which is an FDA approved device for use in infants, placed between the endotracheal tube and the ventilator tubing.

If you are in Group 1, you will receive the usual approach to treatment for babies with routine pressure ventilation as is the current standard of care. A flow sensor device will be placed between the breathing tube and the ventilator tubing, but this reading will be not available to your caregivers, and no intervention will be made based on the readings about the breath size on the monitor and we will only collect observational data.

If you are in Group 2, you will receive the experimental approach to treatment. The reading of the breath size (only the monitor screen data) will be available to your care providers. Based on the volume of the breaths, they will increase or decrease the pressures provided on the pressure generating device to achieve the ideal volume of the breath (tidal volume) for a baby of that particular weight, which is about 4-6 ml/kg/breath. The downloaded data from the monitor will not be available to anyone outside the study team members.

CLINICAL TRIALS RANDOMIZATION



When	What happens
<u>Study Day 0-2</u> (first 48 hours of life)	Deferred Consent (after birth of the baby). Infant in both groups will have tidal volume measured in the delivery room and continued for 48 hours. Group 1: Will receive routine care as recommended by the Neonatal Resuscitation Program (NRP), which is the guiding body for Neonatal resuscitation practices. Group 2: Will receive volume targeted ventilation by modifying the pressure to obtain goal tidal volume.
Day 3 onwards (after the first 48 hours)	Continue on routine respiratory care per standard in the NICU.

The following data will be collected from your medical records/charts

- We will collect information from the medical record regarding the pregnancy and any pregnancy complications. We will gather information regarding your oxygen and breathing support requirements throughout your NICU stay. We will collect information on lab results

which are routinely obtained in the NICU. We will also collect information about other complications of prematurity that may occur during your NICU hospitalization. Occasionally, we may need to review the mother's chart, if the maternal information is not documented in your chart.

- No extra lab work or test will be performed other than the routine blood work that is obtained on all premature infants in the NICU.

Identifiers might be removed and the de-identified information or data may be used for future research without additional informed consent from you.

WHAT RISKS OR PROBLEMS COULD YOU HAVE BY BEING IN THIS STUDY?

Volume targeted ventilation is performed in the NICU, and is considered standard of care in the NICU. We are considering starting volume targeted ventilation in the delivery room itself. There will be two groups in the study.

Group 1 (control arm) will receive the standard routine practice of pressure ventilation in the delivery room, whereas Group 2 (intervention arm) will receive volume ventilation in the delivery room. We will compare the outcomes between the two groups.

For infants in both groups:

- Adding less than 1ml of dead space (extra volume of air in the ventilator circuit) within the flow sensor, which may or may not be of any clinical significance.
- Potential risk of loss of patient information and medical data.
- As with any research study, there may be risks that are not known at this time.

Risk specific to Group 1:

- In addition to the above mentioned risk, infants in the group 1 will not have any direct risk as they would receive routine care as per the standard practice.

Risk specific to Group 2:

- Infants in Group 2 will receive the same routine care with additional information about the breath size or volume (tidal volume) being delivered to the infant. The provider can adjust ventilator pressure to reach goal (appropriate) tidal volume, which may be of potential benefit for you, as in current practice the delivered tidal volume is unknown and you may be receiving too big or too small breaths.

In addition to the above mentioned risk, the investigators do not anticipate any reasonably foreseeable risk to you. We will closely monitor for any unexpected risk or complications that may develop in both the study group.

WE WILL DO THE FOLLOWING TO DECREASE THE RISKS OF THIS STUDY:

- We will limit the maximum pressure that may be used to achieve the goal breath size to <30 cm of water for 60 seconds if you are in Group 2, as it would be considered out of the normal to require more than this much pressure in the immediate newborn period.

- To prevent the risk of loss of patient information and medical data, we will save all data in a password protected online data base (RedCap Database) and remainder of the paper documents will be saved in the secure location in the principal investigators locked office.

WILL YOU BENEFIT FROM BEING IN THIS STUDY?

You may or may not benefit from being in this study. It is possible that in the intervention arm with volume targeted ventilation, it may offer some protection from lung injury, but we don't know if this will happen for sure.

If randomized into the control arm, we do not expect that you will personally benefit from being in this research study. What we learn from this research study may help other premature infant with immature lungs in the future.

WILL YOU SHARE ANY RESULTS WITH ME?

It may be several years before the results of the research are available. If you would like us to try to reach you at that time, please let us know. We will ask for your contact information. We are not performing any extra laboratory tests in you, other than routinely performed tests in the NICU.

WHAT OPTIONS OTHER THAN THIS STUDY ARE AVAILABLE TO YOU?

You do not have to join this study to get treatment. Other options include receiving regular care without getting enrolled in the study.

WILL BEING IN THE STUDY COST YOU ANYTHING?

Use of the device will not cost anything to you. There will be no additional cost to you due to participation in the study. Usual medical care costs include those services that are considered medically necessary to manage your condition will be the same. The costs of usual medical care will be the responsibility of you or your insurance and may include deductibles and co-payments.

WILL YOU RECEIVE ANY PAYMENTS OR GIFTS FOR PARTICIPATING?

No payments or gifts will be provided for participating in this study.

WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF TAKING PART IN THIS STUDY?

The term "research-related injury" means an illness or injury that is a direct result of the treatment, or procedures required by the protocol, which you would not have been exposed to had you not participated in the research study.

If you experience an illness or injury while in this study, please contact your study doctor and, if needed, seek treatment. If you are treated at a Baystate facility, and it is determined that your illness or injury was a direct result of your participation in this study, you will not be responsible for the costs. If you are treated somewhere else, your usual healthcare coverage would apply and you may be responsible for part or all of those expenses.

Baystate does not have funds set aside to compensate you or pay for medical costs beyond those needed for the immediate evaluation and treatment of your illness or injury.

HOW WILL YOUR PRIVACY AND INFORMATION ABOUT YOU BE PROTECTED?

We will protect your privacy as a participant in this research study and the confidentiality of your research information. Your study file will be stored in a secure area in the newborn medicine office in a locked cabinet. We will assign a code to each

Study participant. Information such as your name will only be available to the investigators and this information will not be shared with anyone outside Baystate Health. We may be required by law to report some information (for example; certain infectious diseases, suspected abuse) to a state agency for public health or safety reasons.

INFORMATION ABOUT THE PRIVACY OF PROTECTED HEALTH INFORMATION

Baystate Health has rules in place to protect information about you. Federal and state laws also protect your privacy. This part of the consent form tells you what information may be collected in this study and who might see or use it.

Generally, only people on the research team will know that you are in the research study and will see your information. However, there are a few exceptions that are listed later in this section of the consent form.

The people working on the study will collect information about you. This includes things learned from the procedures described in this consent form and may include information from your medical record if needed for the study. They may collect other information including your name, address, date of birth, and other details.

The research team will need to see your information. Sometimes other people at Baystate may see or give out your information. These include people who review the research studies, their staff, administrative personnel, or other Baystate staff.

The fact that you are taking part in this study and information from procedures (such as lab tests) that are done for the research may become part of your medical record.

If we publish information from this research study or use it for teaching, your name will not be used.

We cannot do this study without your permission to use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside of Baystate who receive your information may not be covered by this promise. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee this.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by contacting the Principal Investigator of this study. The Principal Investigator can be reached at:

Ruben Vaidya, MD
759 Chestnut St, Springfield, MA 01199
Phone: 413-794-5370
Fax: 413-794-5100

If you send a letter, please be sure to include the study name and your contact information.

If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

You can ask to see your research records, but sometimes that can only happen after the research is completed. If you would like to see your research records, please discuss this with your study doctor or a member of the research team.

WHO DO YOU CONTACT IF YOU HAVE STUDY QUESTIONS OR CONCERNS?

If you have any questions about this study, if you feel you developed any complication related to the study, please contact: *Ruben Vaidya, MD* at 413-794-5370. After hours, please call *the Neonatal ICU, and request to speak to the on call attending Neonatologist, and he/she will be able to contact the study's Principal Investigator, Dr Ruben Vaidya.*

If you would like to discuss your rights as a research participant, or wish to speak with someone not directly involved in the study, please contact the Baystate Institutional Review Board (IRB) at (413) 794-4356.

STATEMENT OF VOLUNTARY CONSENT

I have read this form or have had it read to me. I have been told what to expect if I take part in this study, including possible risks and possible benefits. I have had a chance to ask questions and have had them answered to my satisfaction. I have been told that the people listed in this form will answer any questions that I have in the future. By signing below, I am volunteering to be in this research study and authorizing the use of my information for the research.

Participant's Name (Print): _____

Signature: _____ Date: _____ Time: _____

(If Applicable) **Legal Representative's Name (Print):** _____

Relationship to Participant (*ex. Parent, Legal Guardian*) (Print): _____

Signature: _____ Date: _____ Time: _____

Witness's Name (Print): _____

Signature: _____ Date: _____

Reason for Use of Witness: _____

STUDY REPRESENTATIVE STATEMENT

I have explained the purpose of the research, the study procedures, the possible risks and discomforts, the possible benefits, and have answered all questions to the best of my ability.

Study Representative's Name (Print): _____

Signature: _____

Date: _____ Time Consent Obtained: _____

You will receive a copy of this form after it has been signed and date