

Official Title: Pragmatic Investigation of Volume Targeted Ventilation-1 (PIVOT-1)

NCT03909854

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Department/Section of Internal Medicine-Pulmonary

Pragmatic Investigation of Volume-Targeted Ventilation-1: Provider Survey

Principal Investigator: Kevin Gibbs MD

SUMMARY

You are invited to participate in a research study. The purpose of this research is to understand provider preference in mechanical ventilation (MV) modes and ultimately improve ventilation practices in the medical intensive care unit (MICU). We hope to gain insight into current MV practices as well as barriers and facilitators to ventilator optimization. This insight will help design future MV projects in the MICU. You are invited to be in this study because you are a member of the MICU team. Your participation in this research will involve completing a questionnaire via a QR code or a hardcopy survey. The survey should take less than 10 minutes to complete. We will not ask for any identifying information (such as your name) in this survey.

Participation in this study will involve completing an anonymous survey via a QR code on your cell phone or a hardcopy survey. All research studies involve some risks. A risk to this study that you should be aware of is providing information you may consider confidential or private. You are not expected to benefit from this study, but participation may go on to benefit patient care in the medical center.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator at [REDACTED]

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [REDACTED] or the Wake Forest University Health Sciences Research Subject Advocate at [REDACTED].

WHY IS THIS STUDY BEING DONE?

Mechanical ventilation practices and decision making in the medical intensive care unit are

often nuanced—involving multiple providers including attendings, house staff, and respiratory therapists. Selection of mode of mechanical ventilation may depend on provider familiarity with the ventilator brand, the modes of ventilation, personal preferences, institutional culture and patient characteristics; however, the factors that inform mode selection are uncertain. Mode selection may impact multiple aspects of patient care and patient outcomes. As a result, there is a significant need to understand provider decision making.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 50 team members will participate in this study.

WHAT IS INVOLVED IN THE STUDY?

As a participant in the research study, you will be asked to complete a questionnaire via a QR code or a hardcopy survey. Questions are regarding mechanical ventilation practices as well as barriers and motivators for mode selection. This information will help inform results of the PIVOT-1 pragmatic trial and inform future trial development.

WHAT ARE THE RISKS OF THE STUDY?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

Taking part in this research study may involve providing information that you consider confidential or private. There is minimal risk of breach of confidentiality. 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.

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 care providers and/or patients in the future.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study. Participation in or results from this study will not impact your evaluations and performance reviews in this study.

WHAT ARE THE COSTS?

There are no costs associated with this study.

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 or permitted by law, or necessary to protect the safety of yourself or others.

WILL YOU BE PAID FOR PARTICIPATING?

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

WHAT ABOUT MY HEALTH INFORMATION?

No information will be collected about your personal health or professional performance history.

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. If you decide to stop participating in the study you can do so by not completing or submitting the survey. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled.

Information about you may be removed from study data and could be used for future research or shared with other researchers without additional consent from you.

By continuing, I agree to take part in this study. I authorize the use of my survey results as described in this consent and authorization form. I have had a chance to ask questions about being in this study and have had those questions answered. By taking part in the study, I am not releasing or agreeing to release the investigatory, the sponsor, the institution or its agents from liability or negligence.