Pen Bay Medical Center
MaineHealth

Official Title: **ATIVO Study – Anticoagulation Therapy in the Very Old**

NCT #: **03103763**

Informed Consent Form Attached

Last patient was consented on 04 AUG 2017.

Document date: 13 MAR 2020

PARTICIPANT INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

STUDY TITLE: Anticoagulation Therapy in the Very Old - ATIVO

STUDY INVESTIGATORS: Robert Stein, MD and Caroline Knight, RN, BSN, CCRP

STUDY SITE: Pen Bay Medical Center

TELEPHONE: 207-921-5757, Dr. Robert Stein
207-921-8959, Caroline Knight, RN

SPONSOR: NONE

You are being asked to take part in a type of medical research called an observational study. Your participation in this research study is strictly voluntary, meaning that you may or may not choose to take part. This consent form describes the purpose, procedures, possible benefits and risks of the study. This form explains how your medical information will be used and who may see it. Before you consent to be part of this study, please read this document carefully. Ask as many questions as you need to be sure that you understand what taking part in the study will involve.

After reading the consent form, if you would like to participate, you will be asked to sign this form. You will be given a signed copy of your consent form to take home and keep for your records.

Take your time to make your decision about participating.

WHAT IS THE PURPOSE OF THE STUDY?

You are being asked to participate in this study because you have been diagnosed with an abnormal heart rhythm (atrial fibrillation or A-Fib) and are in one of the age groups we are studying.

The purpose of this study is to better understand how elderly patients diagnosed with A-Fib are cared for by their health-care provider and what happens to them as a result of the care they receive, and in particular, the drug therapy they receive and their associated outcomes. Being enrolled in this observational study means that you will be cared for just as you would be if you were not enrolled, however, information will be gathered from you and your health-care providers.

HOW MANY PEOPLE WILL TAKE PART IN THE REGISTRY?

Up to 270 men and women who are diagnosed with A-Fib are expected to participate. All patients aged 90 or older will be asked to participate. It is anticipated that this group will involve no more than 90 participants. An equal number of patients diagnosed with A-Fib who are aged 80-89 years will be asked to participate. Additionally, an equal number of patients diagnosed with A-Fib who are aged 70-79 will be asked to participate. This study is only being done at Pen Bay Medical Center.

HOW LONG WILL I BE IN THIS REGISTRY?

Your participation in the study will begin when you sign this informed consent form and will last approximately two (2) years.

WHAT PROCEDURES WILL BE DONE IF I VOLUNTEER AND AM SUITABLE FOR THIS REGISTRY?

A member of the study team will provide you with detailed information about this study during your enrollment visit. If you agree to participate in the study, you will be asked to read and sign this Participant Informed Consent Form and Authorization to Use and Disclose Medical Information. If you are eligible, you will be asked to provide information about your A-Fib medical history, and any other medical conditions and treatments. Your regular follow-up visits related to your treatment and care of A-Fib are not part of the study.

Information will be collected at the time of your enrollment, and then at 6 months, 12 months, 18 months, and 24 months after your enrollment. You will not need to do anything to help with the collection of this information.

WHAT ARE THE POSSIBLE RISKS OF BEING IN THE REGISTRY?

The only requirement of this registry involves the review and collection of information from your medical records. There are no risks of injury or illness associated with participating in this study.

WHAT ARE THE BENEFITS OF BEING IN THE REGISTRY?

There is no direct benefit to you for participating in this study, but the information may help in improving treatment for elderly A-Fib patients in the future.

WHO PAYS FOR THE REGISTRY? WILL I BE PAID FOR TAKING PART IN THE STUDY?

There are no anticipated costs to you for participating in this study. There is no sponsor paying for this study.

You will not receive any payment for your participation in this study.

WHAT ARE THE ALTERNATIVES?

The only alternative is not to participate in this study.

WHAT HAPPENS TO THE INFORMATION COLLECTED ABOUT ME?

Your protected health information includes information from your existing medical records, such as your date of birth and initials, and new information about you that is collected during the study.

Members of PenBay Healthcare Institutional Review Board ("IRB") (which oversees the conduct of this registry), may review your medical records to verify study procedures.

The study team will keep your personal medical records and a list that links each participant's name to his or her code number for at least 5 years. During that time they will be kept confidential to the extent permitted by law.

The results of the study may be published in a medical journal, or presented at meetings for educational purposes. If the results of the study are published, you will not be personally identified and your identity will not be disclosed.

By signing this form, you are permitting direct access to and use of your medical records and information by the individuals and entities identified above for the purposes described.

WHAT IF I CHANGE MY MIND AND DO NOT WANT TO BE IN THE REGISTRY ANYMORE?

Your participation in this study is voluntary. You can agree to be in the registry now and change your mind later. Your decision will not affect your regular care or the benefits to which you are otherwise entitled.

If you agree to participate in the registry and later change your mind, call Caroline Knight at 207-921-8959 or Dr. Robert Stein at 207-921-5757.

If you cancel your permission after you have started in the study, the study team will stop collecting your health information.

WHOM DO I CONTACT FOR INFORMATION?

If you have any questions about the registry, please contact the Caroline Knight at 207-921-8959 or Dr. Robert Stein at 207-921-5757.

If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer input, you may contact the PenBay Healthcare Institutional Review Board at 207-921-8490 or 594-4244.

AGREEMENT TO TAKE PART IN THE STUDY

This study has been explained to my satisfaction. My questions about the study have been answered. Based on this information, I volunteer to take part in this study. I will receive a copy of this signed informed consent form and authorization.

_____
Printed Name of Participant, in full

_____ _____
Signature of Participant Date

_____
Printed Name of Legally Authorized Representative (optional)

_____ _____
Signature of Legally Authorized Representative (optional) Date

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date