Official Title: Second Time's the Charm: Evaluation of pharmacist interventions in lipid management for secondary prevention
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Evaluation of Pharmacist Interventions in Lipid Management for Secondary Prevention

Informed Consent Form to Participate in Research

Principal Investigator: Kayla Marvin, PharmD, BCACP, CDCES, CPP

SUMMARY

You are invited to participate in a research study. This project's primary objective is to compare the effect of pharmacist intervention versus standard of care on the implementation of guideline directed therapies for elevated cholesterol. Patients with a history of cardiovascular disease are at an increased risk of future heart attack or stroke. Therefore, guidelines recommend providers use medication to lower LDL to a goal of less than 55. Patients with a history of cardiovascular disease and recent LDL greater than 55 will be included in this study. You are invited to participate in this study because you meet these criteria. Patients included in the study will be randomized and placed into 2 groups – standard of care or pharmacist intervention. If you agree to participate in this study, you will be included in the pharmacist intervention group at the recommendation of your primary care provider. Your participation in this study will involve at least one in-person visit with a pharmacist and follow-up phone visits with a pharmacist as needed. We may also ask you to present to a lab for a repeat lipid panel if we need to make medication changes. The study will take place over the course of several months (anticipated November 2024-March 2025). You may have only one visit or several visits with a pharmacist during this study period. At the end of the study, you may opt to continue having pharmacist involvement in your care.

Any interventions by the pharmacist will be within normal scope of practice. You may or may not benefit personally from these interventions as pharmacists can closely monitor your progress when starting or changing medications and may follow up sooner than your primary care provider. Any labs or medication changes will be authorized by your physician and will not be collected for research purposes.

Your participation in this study is voluntary. You can decline pharmacist services and continue having your primary care provider solely manage your cholesterol. You will not lose any services, benefits, or rights you would normally have if you chose not to participate.

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

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

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 75 people will take part in the pharmacist intervention group of this study. Another 75 people will be included in the standard of care group.

WHAT ARE THE RISKS OF THE STUDY?

The risk of harm or discomfort that may happen as a result of taking part in this study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. A pharmacist may recommend you start a new medication as part of this study. This medication has the potential to cause side effects. You will be informed of all potential side effects prior to being prescribed medication. You should discuss the risk of being in this study with the study staff.

There is a small risk of breach of confidentiality. We will do our best to protect your confidential information. Various efforts will be made to keep your information safe, including coding research records, keeping records under password protection and allowing only authorized personnel access to your information.

As part of this study, you will be asked questions about your cholesterol treatment, monitoring, and barriers to care. Your responses will be stored in your medical record in the same way as they would be for any medical office visit.

WHAT IF I AM HARMED BY 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 University 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 University 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 contact the principal investigator at the telephone and address listed on the first page of this form.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You may or may not personally benefit from participation in this study. Studies show lower LDL levels lead to a reduction in risk of developing heart disease. The purpose of this study is to lower your cholesterol to goal, which may reduce your risk of further cardiovascular adverse outcomes.

WHAT ARE THE COSTS?

The cost of this study will be a standard office visit charge for your one in-person appointment with a pharmacist. This charge is the same for any patient seeing a pharmacist in clinic. All telephone follow up will be free of charge. As part of this study, you may be prescribed additional medication therapy. You will be financially responsible for any medication cost not covered by insurance, copay cards, vouchers, or other patient assistance programs.

WILL 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 authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always a small risk that de-identified information will 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.

WHAT ABOUT MY HEALTH INFORMATION?

In this study, any new information we collect about your health or behavior is considered Protected Health Information. The information we collect for this research study includes basic demographics, cholesterol results, and cholesterol treatment. Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time, any research information not already in your medical record will be either destroyed or de-identified.

Any research information entered into your medical record will be kept for as long as your medical record is kept by Atrium Health Cabarrus. 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 finished.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will 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) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

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.

You may inform Kayla Marvin, PharmD 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:

Kayla Marvin: [redacted]

If you have any questions or concerns or would like to speak to the investigators, please contact Lyndsi Roland at [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.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

You may choose not to take part or leave the study at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff. The investigators also have the right to stop your participation in the study at any time. This could be because you no longer meet criteria for participation, it is in your best medical interest, your provider does not think you are a good candidate, or because the entire study has been stopped. Information about you may be removed from the study data.

By continuing, 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. I have had a chance to ask questions about being in this study and have those questions answered. By taking part in the study, I am not releasing or agreeing to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

SIGNATURES

Subject Name (Printed):_____Date: _____Time:_____ am pm

Subject Signature: _____Date:_____ Time:_____ am pm

Person Obtaining Consent: _____