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Wake Forest University
School of Medicine

Department of Emergency Medicine

EMERGENCY MEDICINE - CARDIOVASCULAR RISK ASSESSMENT FOR LIPID DISORDERS (EMERALD)

Informed Consent Form to Participate in Research
Simon Mahler, MD, MS, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to determine the effectiveness of patients starting medication for high lipid levels (hyperlipidemia) after visiting the Emergency Department. You are invited to be in this study because you have presented to the ED with chest pain and may have hyperlipidemia. Your participation in this research study will involve today's enrollment and 1 follow-up visit.

Participation in this study will involve running an ED lipid panel lab in the Emergency Department, starting the study medication, which is either a moderate- or high-intensity statin, and a 30-day research follow-up visit where we will recheck your lipid panel.

All research studies involve some risks. A risk to this study that you should be aware of is the risk associated with taking the study medication, statins. You may or may not benefit from participation in this study.

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. Some other choices may include receiving the standard of care treatment in the emergency department. You could also receive a referral for outpatient care. 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 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, Simon Mahler 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].

INTRODUCTION

You are invited to be in a research study. Research studies help scientists learn new information that may help other people in the future. You are being asked to be in this study because you have chest pain and may have hyperlipidemia. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. 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?

This study is being done to determine the effectiveness of initiating medication for hyperlipidemia (HLD) in the ED. Hyperlipidemia is a key risk factor that is associated with heart disease, which is one of the leading causes of death in the US. However, patients are rarely screened for Hyperlipidemia in the ED and ED providers rarely initiate medication for hyperlipidemia. Thus, there is a clear opportunity to improve health for the patients who present to the ED with undiagnosed and/or unmanaged hyperlipidemia.

By starting a statin, which are an already approved class of medication by the U.S Food and Drug Administration (FDA), patients can potentially start to manage their hyperlipidemia after being treated in the ED.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

20 subjects will take part in this study

WHAT IS INVOLVED IN THE STUDY?

For patients enrolled, the following will occur:

1. Your provider will order a lipid panel today in the ED,
2. Your provider will then determine if you should be on a statin medication
3. Your provider will then prescribe a statin in the ED,
4. During the 30 days before your follow-up appointment, you will complete a drug diary daily.
5. You will then complete the 30-day follow-up visit to recheck your lipid panel.

If you take part in this study, you will have the following tests and procedures: You will have approximately 5 teaspoons of blood withdrawn from a vein on 2 occasions to test your lipid panel. The total amount of blood withdrawn during the study will be approximately 10 teaspoons. A pregnancy test may also be performed as standard of care if you are a female of child-bearing capacity.

When you depart from the emergency department you will have 7 days to pick up your study medication, a statin which is prescribed to you by an Emergency Medicine provider. The prescription will be sent to the pharmacy of your choice. You can choose to complete your drug diary daily through Redcap surveys or on paper. A drug diary allows us to capture if you took

your medication daily and if you had any side effects. You will be asked to return for a 30-day follow-up visit to retest your lipid panel. At the 30-day follow-up, you should bring your paper drug diary if you chose to complete it this way.

You will then be prescribed the study drug for up to 30-days as long as no serious side effects occur. If you experience any side effects please follow-up with your primary care doctor or call Dr. Simon Mahler at [redacted]. You can also refill the prescription through your PCP. If you do not have a PCP at the initial enrollment, we will refer you to one.

How Long Will I Be in the Study?

You will be in the study for about 30 days. There is 1 follow-up which occurs around the 30-day mark from ED enrollment.

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 first.

What are my responsibilities if I take part in this research?

If you agree to take part in this study, you must take the study treatment as instructed and do all study test and assessments. It is important that you follow the instructions from your study doctor. It is also important that you tell study staff about any other medicines, vitamins or herbal supplements you are taking before and during the study. You should especially tell your healthcare professional if you take blood thinners, medications for HIV/AIDS, and/or medication for preventing pregnancy as these drugs may have contraindications with the study drug.

You should also tell your health care professional before taking the study drug if you have a history of muscle pain or weakness, drink more than 2 glasses of alcohol daily, have liver problems, have kidney problems, have thyroid problems, and are Asian or of Asian descent.

If you are female, you must not be pregnant or breast-feeding. Tell your study doctor if you are pregnant, are attempting to become pregnant or are breastfeeding. If the pregnancy test is positive you will discontinue treatment with study medication in the study. We will not retest you in the Emergency Department if your initial pregnancy test is positive. If you become pregnant during the study you should notify the study doctor right away and you should stop study medication.

You should inform your study doctor or the study staff of any concerns you may have or any new health issues you may experience

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. You may experience no side effects, some or all of these. Risk and side effects of taking statins include:

- Muscle problems/muscle pains,
- Headache,
- Dizziness,
- muscle pain,
- low blood platelet count,
- liver damage,
- kidney damage,
- myalgia,
- abdominal pain,
- asthenia,
- nausea

It is also not possible to rule-out the chance of an allergic reaction to the study drug. Some symptoms of allergic reactions are mild (hives, itching) while others can be life-threatening (difficulty breathing, swelling of the throat). If you have difficulty breathing and/or swelling of the throat (a life-threatening allergic reaction), call 9-1-1 and contact Dr. Mahler [redacted].

You may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally some people become dizzy lightheaded or feel faint. Infection may occur on rare occasions. Frequent donation of blood can result in low iron in your blood (iron deficient anemia).

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.

There also may be other risks 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 to your health.

Reproductive Risks and other Issues to Participating in Research

Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, OrthoEvra patch, NuvaRing, intrauterine devices (IUD), Nexplanon implant, DepoProvera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a diaphragm with spermicide with Plan B

used for any noticed condom or diaphragm failures. We encourage you to discuss this issue further with your physicians if you have any questions.

Pregnant women are excluded from participation in this study. Because NO method of birth control is 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?

If you agree to take part in this study, there may or may not be direct benefit to you. Because individuals respond differently to the study medication, no one can know in advance if it will be helpful in your case.

Just by taking part in this research study, you may be helping future patients by providing important information about the standard of care provided in the emergency department by contributing to future medical knowledge.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study. You should talk to the research staff about all the choices you have. Instead of being in this study, you have these options: Receiving standard of care in the emergency department, seeing an outpatient provider, being prescribed a statin if applicable even if you do not take part in the study.

WHAT ARE THE COSTS?

Study costs, including the initial lipid panel, and other costs related directly to the study, will be paid for by the research study. The 30-day visit costs, including the 2nd lipid panel, will also be covered for by the study. Costs for your regular medical care and for the research study medication, are your own responsibility and will be charged to your insurance.

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.

Your 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.

_____ I give permission to Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to contact me by text message at the number I provided to send information, reminders, and to communicate with me about the research study. I understand that I am responsible for the standard text message rate of my carrier. I also understand that text messaging is not a secure form of communication and I accept the risk that individuals not involved in the

research study may be able to access the text messages. I also understand that texting is not to be used for emergency situations.

_____ By providing my email address, I give permission for Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid $25 if you complete the scheduled study visit. If you withdraw for any reason from the study before completing the 30-day visit you will not be paid.

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

Wake Forest University Baptist Medical Center maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of injuries or illnesses to some participants in certain research studies. 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. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

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 Simon Mahler at [redacted].

WHAT ABOUT MY HEALTH INFORMATION.

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** demographics, lab values, medications, medical history, other test results and contact information.

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 will be used to help treat you, arrange payment for your care, or assist with the health care operations of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

If you choose to participate in this study, your medical record at Atrium Health, Wake Forest University Health Sciences, or their respective affiliated entities 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. Authorization to access this part of the medical record will only be available to people who have a need to know this information in order to perform their job-related duties. If you are not a patient of these health care facilities, a medical record will be created for you anyway to provide access to this important information to providers in case of an emergency.

We will take steps 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 Atrium Health Facilities; 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, videotapes, audiotapes or other recorded media which are identify you unless we you're your written authorization.

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 at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed, or it will be de-identified 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 Dr. Simon Mahler 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:

Simon Mahler, MD
[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.

Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Atrium Health, Wake Forest University Health Sciences, and/or their respective affiliated entities. These results and reports will be kept secure in compliance with applicable laws, with permission to access this information limited to individuals with proper authority, but who may not be directly involved with this research study.

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, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

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

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.

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, Dr. Simon Mahler at [redacted]

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] or the Research Subject Advocate 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 (Printed):_____

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