Evaluation of Wall *S*hear Stress and Neointimal *He*aling Following Percutaneous Coronary Intervention of *A*ngulated Vessels with *R*esolute® Integrity Zotarolimus Eluting Coronary *Stent* Compared to XIENCE XPEDITION® Everolimus Eluting Coronary Stent (*SHEAR-STENT* Study)

NCT02098876

Date: **December 10, 2015**
IRB number: 00066353

Emory University
Consent to be a Research Subject

Title: The Evaluation of Wall Shear Stress and Neointimal Healing Following Percutaneous Coronary Intervention of Angulated Vessels with Resolute® Integrity Zotarolimus Eluting Coronary Stent Compared to XIENCE Xpedition Everolimus Eluting Coronary Stent (SHEAR-STENT Study)

Principal Investigator: Habib Samady, MD, FACC, FSCAI

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

Study Overview

You are being invited to participate in this international multi-site study because you are undergoing a medically necessary cardiac catheterization. If your doctors find narrowings in your heart arteries that they think require unblocking, they might consider treating you with FDA-approved stents that have been shown to be safe and effective. Stents are tubular metallic supports that are delivered over small balloons to your heart blood vessel through small catheters inserted in your groin or wrist blood vessels. The purpose of this study is to compare how well your blood vessels responds to either the Resolute® Integrity stent or XIENCE Xpedition® stent (both commonly used stents in clinical practice) immediately after implantation and to study the healing of your blood vessel over time. Study participants will return to the Cardiac Catheterization laboratory to repeat the study in 12 months.

Up to 60 subjects will be enrolled in this study at Emory with up to 630 subjects total enrolled worldwide. We anticipate 80% of subjects will be excluded (screen-failed) due to predefined inclusion criteria. An estimated 126 subjects will complete baseline evaluation, with an additional 20% of subjects anticipated to withdraw or screen-fail before the follow-up visit, leaving approximately 100 subjects completing the study.

Procedures

If you choose to be in this study, you will be asked to read and sign this consent form after all of your questions have been answered. To evaluate your ability to take part in this study, your cardiologist will review your complete medical history. You should tell your doctor about your relevant medical history, about any medications you are taking, and if you are participating in any other studies or trials. You should also tell your doctor if you are, or suspect you could be pregnant.

If you agree to join this study, certain tests will need to be performed. At the time of enrolment into the study, subjects will be assigned to receive either of the two stents (XIENCE XPedition or Resolute Integrity) using an automated system of randomization. All proposed procedures will be performed only by investigators certified to perform these procedures. The heart catheterization is ordered by your doctor and will be performed as part of your regular care. There will be a separate consent for your catheterization procedure. Data on laboratory tests routinely performed during the procedure and other clinical data will be collected for research purposes.

We will be recording and reviewing the data that is being accrued as a result of subject's standard medical treatment.

	Baseline/ Procedure	**Discharge**	**6 Month (±30 days)**	**Follow-up Procedure at 12 months**
Location of contact	Hospital	Hospital	Phone Call	Hospital
Demographics	X			X
Pregnancy Test	X			X
Medical History (incl. physical exam)	X			
12 Lead ECG	X	X		X
Blood Sampling	X	X		X
Angiogram	X			X
OCT Pullback	X			X
Investigator Treatment Decisions	X			X
Resource Utilization	X	X	X	X
Cardiac Medications Assessment	X	X	X	X
Adverse Events Assessment	X	X	X	X

Risks and Discomforts

Risks associated with the normal standard of care:

1) For the cardiac catheterization, the risks have been detailed in the consent for the catheterization procedure and are not part of the research. These risks are present whether or not you participate in this research study. Cardiac catheterization can cause temporary discomfort at the skin puncture or incision site in the area or groin, bleeding, bruising, clot formation, infection, irregularities in the heart beat, and in very rare instance (less than 0.5%), heart attack, stroke or death.
2) You will be exposed to radiation from fluoroscopy. Some of these procedures are not necessary for your medical care and will occur because you participate in this study. The estimated radiation dose that you will receive is equal to or less than the annual radiation exposure limit allowed for persons who are occupationally exposed to radiation (for example, x-ray technologist, radiologist). The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life.

The risk for radiation-induced cancer from this study is minimal. You will receive radiation exposure from the fluoroscope that produces pictures of your internal organs. Your soft tissue and bones will receive a radiation exposure, but the highest radiation exposure will be to your skin. Very high skin exposure can cause reddening of the skin, blistering and even ulceration. Sometimes this will be delayed for weeks or months after exposure. If you should experience skin discomfort in the area that was pictured, report this to your personal physician.

Risks associated with the Investigation:

1) Intravascular Ultrasound (IVUS) and Optical Coherence Tomography (OCT): During today's study, the risk for investigational purpose is related to passing the IVUS and OCT catheters over the wire used for delivery of the stent. IVUS and OCT are like miniaturized cameras that take pictures of the inside of the heart blood vessel before and after deployment of the stent. These procedures are associated with the possibility of the artery constricting for a short time (known as spasm), tearing the artery wall (known as dissection), and clot formation (known as thrombosis). The risk of transient spasm is less than 3% and is reduced with nitroglycerine and resolves by removing the catheter. The other complications including dissection and thrombosis are very rare (less than 4 in 1000). IVUS and OCT imaging are generally considered safe and frequently used by your doctors to guide the size of stent and to assure that they are well deployed in your heart blood vessel.

2) You will be asked to return for a cardiac catheterization procedure in 12 months to undergo catheterization and take additional pictures on the blood vessel treated with the stent. The purpose of this is to examine how well the stent has healed in your heart blood vessel and whether your body has grown scar tissue in or around the stent that will be placed. The risk of that procedure includes the previously mentioned risk of catheterization (under normal standard of care), and that of IVUS, and OCT (section 1 of investigation).

3) In addition, it is possible in any experiment that side effects, which are not now known, could occur. Precautions will be taken to prevent harmful side effects. If you are pregnant, we want you to tell us and we will not include you in the experiment, because to do so might be harmful to your unborn baby. We also want you to avoid getting pregnant during this study and expect you to use an effective method of birth control. If you should become pregnant in spite of taking precautions, please immediately contact the investigator whose phone number is listed on this form and he/she will provide you with information and/or resources for your consideration.

New Information

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Benefits

There is no guarantee or promise that you will receive any benefit from participating in the study. Future subjects participating in vessel image and stent studies may benefit from the experience gained in this study.

Compensation

There will be no compensation to you for participating in this study.

Other Treatment Outside this Study

If you decide not to enter this study, there is care available to you outside of this research. The study doctor will discuss these with you. You do not have to be in this study to be treated for your stenosis (blockage) in your coronary arteries and the necessary stent(s) can be placed in the blocked artery for you without needing to participate in this study.

Confidentiality

Certain offices and people other than the researchers may look at your medical charts and study records. Government agencies, Emory Healthcare employees overseeing proper study conduct may look at your study records. Study sponsors may also look at your study records. These offices include the Office for Human Research Protections, Medtronic Inc. (the sponsor), the Emory Institutional Review Board, the Emory Office of Research Compliance, and the Office for Clinical Research. Emory Healthcare will keep any research records we produce private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Research Information will NOT go into the Medical Record. However, information on the type of stent you received will be made available on your medical records for your treating physicians to access.

If you are or have been an Emory Healthcare patient, you have an Emory Healthcare medical record. If you are not and have never been an Emory Healthcare patient you do not have one. Please note that an Emory Healthcare medical record will not be created for you just because you are in this study.

Emory does not control results from tests and procedures done at other places. So these results would not be placed in your Emory Healthcare medical record. And they will not likely be available to Emory Healthcare to help take care of you. Emory Healthcare also does not have control over any other medical records that you may have with other healthcare providers. Emory Healthcare will not send any test or procedure results from the study to these providers. So if you decide to be in this study, it is up to you to let them know.

Some tests and procedures that may be done during this study will be reviewed only for research purposes, not for your healthcare purposes. These results will not be reviewed to make decisions about your personal health or treatment. For safety reasons, however, some basic information will be placed in your Emory Healthcare medical record:

- The fact that you are enrolled in a research study and you gave informed consent to join it
- Contact information for the researcher who is in charge of the study

We encourage you to let your health care provider know if you decide to take part in this study. That way, they can have extra information that can help them to make decisions about your health care.

In Case of Injury

If you get ill or injured from being in the study, Emory would help you to get medical treatment. Emory and the sponsors have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proved that your injury or illness is directly caused by the negligence of an Emory or sponsor employee. “Negligence” is the failure to follow a standard duty of care.

If you become ill or injured from being in this trial, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Habib Samady at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

Costs

You will have to pay for the items or services for which the study sponsors do not pay. The sponsors will not pay for your regular medical care. If you have insurance, Emory will submit claims to your insurance for items and services that the sponsor does not cover. Emory will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid. When you return for a follow up cardiac catheterization in 12 months, the sponsors will cover all costs of the follow-up study visit.

The actual amount that you have to pay depends on whether or not you have health insurance. The sponsor of the study will cover costs associated with the research portion of the procedure. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interest;
- You were to object to any future changes that may be made in the study plan; or
- For any other reason.

Contact Information

Contact Dr. Habib Samady at (404) 778-5299:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent

Please print your name and sign below if you agree to be in this study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed consent to keep.

Name of Subject

Signature of Subject Date Time

Signature of Person Conducting Informed Consent Discussion Date Time

Name of Person Conducting Informed Consent Discussion

Signature of Legally Authorized Representative with authority for research decisions Date Time

Authority of Legally Authorized Representative or Relationship to Subject