A Two Year Multicenter Study of Robotic-Arm Assisted THA: Acetabular Cup PlacementAccuracy and Clinical Outcomes

22JUL2019

NCT: 03891199

More Than Minimal Risk
Consent and HIPAA Form

Principal Investigator	Brock A. Lindsey, MD
Department	Orthopaedics
Protocol Number	1808218345
Study Title	A Two Year Multicenter Study of Robotic-Arm Assisted THA: Acetabular Cup Placement Accuracy and Clinical Outcomes
Co-Investigator(s)	Matthew J. Dietz, MD; Benjamin M. Frye, MD; Adam E. Klein, MD; T. Ryan Murphy, MD
Sponsor (if any)	Stryker
Study Personnel	Jennifer Eicher, Sheila Rye, Sherri Davis

Contact Persons

In the event you experience any side effects or injury related to this research, you should contact Dr. Brock A Lindsey at (304) 293-1317. (After hours call 304-598-4000 and ask for the Orthopaedic Resident on call). If you have any questions, concerns, or complaints about this research, you can contact Dr. Brock A. Lindsey at (304) 293-1317.

For information regarding your rights as a research subject, to discuss problems, concerns, or suggestions related to the research, to obtain information or offer input about the research, contact the Office of Research Compliance at (304) 293-7073.

Introduction

You, _____, have been asked to participate in this research study, which has been explained to you by _____. This study is being conducted by Brock Lindsey, MD in the Department of Orthopaedics at West Virginia University with funding provided by Stryker.

Purpose(s) of the Study

It has been explained to you that you are a candidate for elective total hip replacement surgery. You have been invited to participate in this research study which involves patient's having total hip replacement surgery. The purpose of this study is to assess how the acetabular cup (the cup shaped socket of the hip joint) is placed and how it affects patient outcomes. WVU expects to enroll approximately 120 subjects; a total of approximately 192 subjects at all sites are expected to participate in this study.

Description of Procedures

This study involves randomizing persons scheduled for elective total hip replacement to one of two surgical fixation methods. The first method is traditional total hip replacement approach and the second method is robotic-arm assisted total hip replacement approach. The surgical approach offered will be based upon chance using a method of selection called randomization (like flipping a coin); your chances of receiving the robotic-arm assisted surgery are approximately the same as that of receiving traditional surgery.

It involves the use of X-Rays and Computed Tomography (CT) scans to assess the placement of the acetabular cup (the cup shaped socket of the hip joint). Two CT scans will be needed during the course of the study; one at your Preoperative Visit (before surgery) and the other at your 3-6 month Postoperative Visit (after surgery). If you are randomized to traditional surgery, you will be required to have 2 CT scans which are not typically standard of care. If you are randomized to the robotic-arm surgery, you will be required to have 1 CT scan at your 3-6 month post- operative visit, which is not standard of care. An initial CT scan is necessary per Standard of Care for anyone having robotic-arm assisted surgery. The CT scan exposes you to additional radiation that you may not be exposed to if you were to have traditional total hip replacement. You will not be eligible to participate if you refuse the CT scans. Regarding the X-Rays, it is standard of care that you have x-rays done at the specified time frames listed above. No additional x-rays will be collected for research purposes.

You will be asked to fill out a questionnaire regarding your ability to do daily activities and your general health state. This will take approximately 12 minutes to complete. You do not have to answer all the questions. You will have the opportunity to see the questionnaire before signing this consent form.

This is a 2-year study, with follow-up appointments at 3-6 months 1-year, and 2-year postoperatively, which are standard procedure for anyone having a hip replacement.

Risks and Discomforts

This study requires you to undergo 2 CT scans of your pelvis. Exposure to radiation is associated with increased risk of cancer. Patients will be exposed to additional radiation from the CT scan 1-2 times over the course of the study based on which TREATMENT METHOD [arm] they are randomized to. The risk of developing cancer as a result of exposure to radiation depends on the part of the body exposed, the individual's age at exposure, and the individual's gender. For the purpose of radiation protection, a conservative approach that is generally used is to assume that the risk for adverse health effects from cancer is proportional to the amount of radiation dose absorbed and that there is no amount of radiation that is completely without risk. The possibility of fatal cancer from radiation is approximately 1 chance in 2000.

This study may involve risks to the unborn child. For this reason, women who are pregnant will not be accepted. If you are a woman who could become pregnant, you will not be allowed to participate in this study until you have had a pregnancy test and the test has indicated that you are not pregnant. You must use a medically approved method of birth control while you are on this study.

There are no known or expected risks from participating in this study, except for the mild frustration associated with answering the questions.

Alternatives

You do not have to participate in this study.

Benefits

Possible benefits for those randomized to the robot assisted surgery approach may be better long term outcomes due to more accurate placement of the acetabular cup.

The knowledge gained from this study may eventually benefit others.

Financial Considerations

You may wish to consult your insurance carrier prior to entering this study.

There are no special fees for participating in this study, but any expense associated with current therapy or treatment of side effects will be billed to you or to your insurance company.

The study sponsor, Stryker, will pay for the additional CT scans that would not be part of the current standard of care. If you are randomized to the robotic-arm assisted approach, your post-operative CT scan will be paid for by Stryker. If you are randomized to the traditional approach both CT scans for the hip surgery will be paid for by Stryker. In addition, you will be reimbursed for your out-of-pocket travel expenses for specific return visits. You will receive $50 gift certificate for returning between 3-6 months post-operatively, and an additional $100 gift certificate for returning at both your 1 and 2-year visits. The study site will reimburse you by check afte you complete a Vendor's Invoice approximately three weeks after such visits. The total amount of gift certificates you could receive for returning for all study follow up visits is $250.

Stryker may use information resulting from the study to develop products or processes from which they may receive a profit. There are no plans to pay you or provide you with any products developed from this research. Stryker will own all products or processes that are developed using information from the study.

Voluntary Compensation

If you are injured as a result of this research, treatment will be available. In the event that you are physically injured as a result of participating in this research, care will be available. You will however, be responsible for the charges for the care. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the investigator, (Brock Lindsey, MD) at (304-293-1317) if you are injured or for further information.

Confidentiality

Any information about you that is obtained as a result of your participation in this research will be kept as confidential as legally possible. Your research records and test results, just like hospital records, may be subpoenaed by court order or may be inspected by the study sponsor or federal regulatory authorities (including the FDA if applicable) without your additional consent.

In addition, there are certain instances where the researcher is legally required to give information to the appropriate authorities. These would include mandatory reporting of infectious diseases, mandatory reporting of information about behavior that is imminently dangerous to your child or to others, such as suicide, child abuse, etc.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US 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 website at any time.

HIPAA

We know that information about you and your health is private. We are dedicated to protecting the privacy of that information. Because of this promise, we must get your written authorization (permission) before we may use or disclose your protected health information or share it with others for research purposes.

You can decide to sign or not to sign this authorization section. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever choice you make about this research study will not have an effect on your access to medical care.

Persons/Organizations Providing the Information

Patient/West Virginia University Hospitals

Persons/Organizations Receiving the Information

- The research site(s) carrying out this study. This includes UHA or UHA Affiliated, WVU, WVU Hospitals. It also includes each site's research staff and medical staff
- Health care providers who provide services to you as part of this research study.
- Laboratories and other people and groups that look into your health information as part of this study in agreement with the study protocol.
- The United State Department of Health and Human Services (which includes the National Institutes of Health (NIH), Food and Drug Administration (FDA)) and other groups that have the right to use the information as required by law.
- Stryker and the people and companies that they use to oversee, manage, or conduct the research.
- The members and staff of any Institutional Review Board (IRB) that oversees this research study.
- West Virginia University Office of Research Compliance and Office of Sponsored Programs.

The Following Information Will Be Used

Information from your existing medical records and new information about you that is created or collected during the study such as: history and physicals, clinic visit notes, nursing and staff notes, laboratory results, x-rays, CT scans, EKG results, demographic data, pulmonary tests, imaging scans and study forms.

The Information is Being Disclosed for the Following Reasons

- Review of your data for quality assurance purposes
- Publication of study results (without identifying you)
- Other research purposes such as reviewing the effectiveness of the robotic-arm assisted total hip replacement.

You May Cancel this Authorization at Any Time by Writing to the Principal Investigator

Brock A. Lindsey, MD, West Virginia University, Department of Orthopaedics, 3400 HSC South, Morgantown, WV, 25606-9196

If you cancel this authorization, any information that was collected already for this study cannot be withdrawn. Once information is disclosed, according to this authorization, the recipient may redisclose it and then the information may no longer be protected by federal regulations.

You have a right to see and make copies of your medical records. You will not be able to see or copy your records related to the study until the sponsor has completed all work related to the study. At that time you may ask to see the study doctor's files related to your participation in the study and have the study doctor correct any information about you that is wrong.

This authorization will expire at the end of the study unless you cancel it before that time.

Voluntary Participation

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time.

Refusal to participate or withdrawal will not affect medical care and will involve no penalty to you. Refusal to participate or withdrawal will not affect your future care, or your employee status at West Virginia University.

In the event new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether or not to continue your participation.

You have been given the opportunity to ask questions about the research, and you have received answers concerning areas you did not understand.

Upon signing this form, you will receive a copy.

I willingly consent to participate in this research.

Signatures

Signature of Subject

Printed Name	Date	Time

The participant has had the opportunity to have questions addressed. **The** participant willingly agrees to be in the study.

Signature of Investigator or Co-Investigator

Printed Name	Date	Time