ClinicalTrial.gov Coversheet

Study Title: Clinical and Economic Comparison of Robot Assisted Versus Manual Knee Replacement

NCT#: NCT01705886

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CONSENT W/O TRACKING

LEGACY HEALTH

APPROVED BY LEGACY IRB
3/8/16
IRB ADMINISTRATOR DATE

Research Study Title: Clinical and Economic Comparison of Robotic versus Manual Knee Arthroplasty
Name of Investigator: Todd Borus, MD
Phone Number: (360) 254-6161
Study Sponsor: Stryker Corp.

1. Introduction

You have been invited to participate in a research study (the "Research Study") being conducted by Legacy Health. You have been invited because you are a candidate for partial joint replacement or total knee replacement because of pain and joint stiffness that interferes with your performance of normal daily activities.

This study will involve 64 patients who are having their knee surgery done at Legacy Salmon Creek. The study investigator will evaluate you for study inclusion/exclusion at your consultation visit. The surgeon will describe the various surgical options that he believes is appropriate for you. You and your doctor will have a discussion and determine which implant is most appropriate for your surgical procedure. Then your surgeon or his assistant will explain the study to you. You will be encouraged to ask questions regarding study participation. Once you are fully informed about the study, you will be asked to sign a consent form. You will also sign a surgical consent form for whichever procedure you and your physician have decided is best for you.

2. Purpose

The purpose of this study is to document and compare the surgical and after surgery costs, recovery time, and outcomes of two procedure types:

- Robotic assisted surgery replacing one compartment of the knee
- Surgeon assisted total knee arthroplasty (Robot is not used)

The expected duration of your participation in the Study is 1 year.

3. Procedures

You will receive a medial unicompartmental knee replacement or a total knee replacement. Your knee consists of 3 compartments: a medial compartment, lateral knee compartment and a patellofemoral knee compartment. Osteoarthritis (OA) can affect one, two or all three of these compartments. Your level of OA will determine which procedure is appropriate for you.

At each physician visit (preoperative, 1-2 weeks postoperative, 4-6 weeks, 10-12 weeks, 6 months and 1 Year) the surgeon or qualified member of the study will perform the following assessments as part of your standard of care:

- Assess the function and range of motion of the knee joint
- Document any complications that may have occurred after surgery
- The surgeon will complete a radiographic assessment of the operated knee post-operatively

In addition to the standard of care given at these follow-up visits, the following will be performed

- A principle investigator or qualified member of the study will complete the Knee Society Score in order to provide a rating of the pain, function, range of motion, and knee joint stability for each patient
- At each clinic visit, study participants will be asked to complete standardized health-related quality of life instruments to document their perception of their pain and function. Patients who undergo knee replacement surgery will complete the following outcome instruments.
    a) The American Knee Society Score is subdivided into a knee score that rates only the knee joint itself and a functional score that rates the patient's ability to walk and climb stairs.
    b) The EQ-5D is a standardized instrument for use as a measure of health outcome. Patients will be also given a questionnaire with questions pertaining to employment, loss of wages, driving, etc.
    c) The Reduced WOMAC is a truncated version of the Western Ontario and McMasters University Osteoarthritis Index. The questionnaire is patient administered and designed to asses pain, disability and joint stiffness in the OA patient.
    d) The KOOS or Knee injury and Osteoarthritis Outcome Score is a patient completed questionnaire to assess the patient's opinion regarding their knee and its associated OA. Poor outcomes are reported with a lower score and good outcomes with a higher score.
    e) The Forgotten Joint Score is a 12-item questionnaire completed by the patient to determine how aware they are of their joint in their everyday life.
    f) Return to function: This form has two parts and will only be completed at your 6-8 weeks follow-up. One part to be completed by a study investigator regarding your recovery while you are recovering as an inpatient. The second portion is completed by the patient and contains questions regarding outpatient recovery.
    g) Progress Report: This document contains 4 questions to be answered only by the patients that receive a robotic-arm assisted implant and will determine their overall satisfaction with their procedure and recovery.

There are a total of 60 questions that should take 10-20 minutes to complete.

In addition to regularly prescribed physical therapy, patients will meet with a physical therapist or qualified member of the study preoperatively for testing to create a starting point. They will also undergo multiple tests/ measurements at 6 weeks and 3-months postoperatively. The physical therapist will create a physical therapy regimen and create an endpoint for the patient. The

endpoint will be goals within reach for each patient to complete before the patient can discontinue physical therapy

- The patient will undergo a series of tests to create an initial starting point preoperatively and post operatively at 6 weeks and 3 months. The tests will be the following:
  - Timed up and Go (TUG) Test: Participants are instructed to stand up from a seated position from a standard chair, walk 3 m around a cone and then return to the chair and resume a seated position. Pace is self-selected. The time to complete the test is recorded.
  - 6 Minute Walk Test (6MWT): Participants are instructed to cover as much distance walking in 6 minutes and can stop and rest if necessary. The course is 30 meters in length, marked at 1 meter intervals with cones marking the turn around point. Distance measured is rounded up to the nearest meter and recorded.
  - Stair Ascend/Descend Test: Participants are asked to ascend and descend 11 steps using a hand rail if necessary. Stair height is 17.8 cm (7"). Pace is self selected. The time to ascend/ descend 1 flight of stairs is recorded.
- An achievable endpoint that the patient will need to meet to conclude the physical therapy is described below. The endpoint will include the following goals for the patient and will be assessed at each post-operative physical therapy visit until patient is discharged from physical therapy:
  - Range of motion 5 to 115 degrees
  - Strength 4/5 for flexion and extension, expressed as a percent of maximal isometric contraction from pre-operative assessment and determined with a dynamometer.
  - Gait with minimal limp without an assistive device for a distance of 250 feet
  - Able to ascend/ descend a flight of stairs with step over gait with good control (and with use of handrail)
- The number visits and duration to reach the endpoint will be tracked by the physical therapist.
- If patient is unable to reach PT D/C criteria by 8 weeks post-op and is unwilling to continue physical therapy, the patient will be discharged from PT at 8 weeks and their current functional state will be recorded.

If you cannot be present in the office, you may be contacted by telephone, mail or email to complete the questionnaires.

Economic data points will also be collected. These data points are specific to the hospital and not the patients. Economic data will include some or all of the following:

Types of cases will be specified for each data point.

Operating Procedure (Knee Arthroplasty)

- Operative time per case type
  - Cost per 10 min of operating room time
- Loss of blood per case type

  - Cost per unit of blood
- Average implant cost per case type
- Other supplies per case type
- Anesthesia amount used per case type
  - Anesthesia costs per case type
- Total billed charges per case type
- Actual costs per case type
- Contribution per case type

Miscellaneous Costs
- Sterilization cost per surgical tray
- Cost per hospital day
  - Regular/Medical bed day
  - ICU bed day

Imaging Costs
- MRI of Knee (with & without contrast)
- CT Scan of the knee

Miscellaneous Data
- Length of stay per case type
- Discharge status of patients per case type

4. Risks / Benefits

This is a minimal risk study which involves collection of data. The purpose of this study is for research purposes only. There is no direct benefit to you to participate in this study. The results of this research study may contribute to clinical research overall and may be published.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

5. Alternatives

This Study does not involve any medical care or other medical procedures, and your only alternative is to refuse participation. You are free to decline participation and should you choose to participate, you are free to withdraw from the Study at any time without penalty or loss of benefits that you would otherwise enjoy outside of the Research Study.

6. **Financial Disclosures**
   a. This study is being conducted and funded by Stryker Corp.
   b. Dr. Borus currently serves as an educational consultant to Stryker Corp. He is reimbursed an hourly rate for training of surgeons learning Makoplasty procedures.

He is also involved in the development of potential future product applications pertinent to Makoplasty total hip replacement surgery that may result in personal financial compensation.

7. **Compensation**

The sponsor will pay you for taking part in the Research Study. You will be given $50 following completion of 3 Month study activities and $50 following completion of 1 Year study activities.

8. Voluntary Participation

a. You are free to refuse to participate or to withdraw from participation at any time and it will in no way affect your relationship with, or treatment at Legacy Health.
b. You will receive a copy of the consent form. You may decline at any time to participate in any or all of these follow-up activities.

9. **Costs**

There is no extra cost to you to participate in this study.

10. Authorization to Use and Disclose Protected Health Information

You hereby authorize Legacy Health to use and disclose your Protected Health Information (PHI) solely for the purposes of the Research Study. PHI includes any portion of your medical records that could be used to identify you such as name, address, birth date, etc.

You hereby authorize the Legacy Health to disclose your PHI to the following Recipient(s): Sponsor of this research, Stryker Corporation, or companies that are working for or with the sponsor.

You hereby authorize Legacy Health to use and disclose your PHI in accordance with the terms and conditions of this Consent Form indefinitely.

Once Legacy Health discloses PHI to the Recipient(s) identified above, Legacy Health cannot guarantee that Recipient(s) will not re-disclose PHI to other persons who may not be bound by this Consent Form, or otherwise be permitted to use or disclose PHI in ways that you did not intend.

You may change your mind and revoke this authorization at any time. To revoke this authorization, you must write to:

Dr. Todd Borus
Address 200 NE Mother Joseph Place, Suite 210

Sponsor: Stryker Corp.

Vancouver, WA 98664
Phone (360) 254-6161

However, if you revoke this authorization, you may no longer be able to participate in the study. In addition, even if you revoke the authorization, the information already obtained by Legacy Health and Stryker Corporation may be used and disclosed as permitted by this authorization and this informed consent.

11. Contacts

Talk to the study doctor and staff about any questions or concerns you have about this study. You should also tell them about any side effects you have. Call the study doctor Dr. Todd Borus at (360) 254-6161.

If at any time during this Research Study, you feel that you have not been adequately informed as to the risks, benefits, alternative procedures, or your rights as a research subject, or feel under duress to participate against your wishes, you can contact Legacy Health's Research Regulatory Specialist who will be available to speak with you during normal working hours (8:30 a.m. to 5:00 p.m.) at (503) 413-5355.

In the event of injury or illness, you should seek medical attention and contact: Principal Investigator, Dr. Todd Borus, ((360) 254-6161).

The subject has been informed of the (i) nature and purpose of the procedures described above including any risks involved in the Research Study's performance; and (ii) of how his or her Protected Health Information may be used or disclosed. The subject has been asked if any questions have arisen regarding these procedures and the subject's privacy rights, and these questions have been answered to the best of the Legacy Health's ability. A copy of this Compound Consent and Authorization has been provided to the subject.

_____ _____

Date [Investigator's Signature or Designee]

I have been informed about the procedures, risks, and benefits of this Research Study and agree to participate. I know that I am free to withdraw my consent and to quit the Research Study at any time. I have read and understand the terms of this Consent Form and I have had an opportunity to ask questions about the Study and to discuss the Study with my doctor and other health care providers and my family and friends. I also have had the opportunity to ask questions about the use and disclosure of my Protected Health Information and my privacy rights. I hereby knowingly and voluntarily authorize Legacy Health to use and disclose my Protected Health Information in the manner described in this Consent Form. I understand that I may decline to participate in this Research Study. I further understand that if I choose to participate, I may withdraw from the Research Study at any time. My decision not to participate in this Research Study or my decision at any time to withdraw from this Research Study will not cause me any penalty or loss of benefits that I am otherwise entitled to enjoy.

_____

Subject's Signature Date

_____

Subject's Legal Representative (if applicable) Date