Rejuvenate Modular Outcomes Study

This study is currently recruiting participants.

Verified May 2012 by Stryker Orthopaedics

First Received on December 8, 2010. Last Updated on May 2, 2012 History of Changes

Sponsor:	Stryker Orthopaedics
Information provided by (Responsible Party):	Stryker Orthopaedics
ClinicalTrials.gov Identifier:	NCT01257568

Purpose

This study will be an evaluation of the Rejuvenate® Modular Hip System for primary total hip replacement (THR) with a cementless application in a consecutive series of patients who meet the eligibility criteria. Subjects will be evaluated for freedom of hip revision at 5 years and clinical outcomes for up to 10 years after surgery.

Condition
Arthroplasty, Replacement, Hip

Study Type: Observational
Study Design: Observational Model: Cohort
Time Perspective: Prospective

Official Title: A Prospective, Post-market, Multi-center Study of the Outcomes of the Rejuvenate® Modular Hip System

Resource links provided by NLM:

MedlinePlus related topics: Hip Replacement

U.S. FDA Resources

Further study details as provided by Stryker Orthopaedics:

Primary Outcome Measures:

- Survival Rate [Time Frame: 5 years postoperative] [Designated as safety issue: No]

  Evaluate the success rate of cementless primary THR with the Rejuvenate Modular Hip System as compared to the Secur-Fit HA monolithic femoral hip stem, through absence of revision at 5 years postoperative.

Estimated Enrollment:	240
Study Start Date:	November 2010
Estimated Study Completion Date:	November 2022
Estimated Primary Completion Date:	November 2022 (Final data collection date for primary outcome measure)

Groups/Cohorts
Rejuvenate Modular Hip System

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No
Sampling Method:	Probability Sample

Study Population

Patients eligible for Total Hip Replacement and meeting the Inclusion/Exclusion criteria at each investigative site will be invited to participate.

Criteria

Inclusion Criteria:

- Patient has signed an IRB approved, study specific Informed Patient Consent Form.
- Patient is a male or non-pregnant female age 18 years or older at time of study device implantation.
- Patient has primary diagnosis of Non-Inflammatory Degenerative Joint Disease (NIDJD).
- Patient is a candidate for a primary cementless total hip replacement.
- Patient is willing and able to comply with postoperative scheduled clinical and radiographic evaluations and rehabilitation.
- Patient's operative femur templates to Rejuvenate® Modular Stem size 7-12.

Exclusion Criteria:

- Patient has a Body Mass Index (BMI) ≥ 40.
- Patient has an active or suspected latent infection in or about the affected hip joint at time of study device implantation.
- Patient has a neuromuscular or neurosensory deficiency, which limits the ability to evaluate the safety and efficacy of the device.
- Patient is diagnosed with a systemic disease (e.g. Lupus Erythematosus) or a metabolic disorder (e.g. Paget's Disease) leading to progressive bone deterioration.
- Patient is immunologically suppressed or receiving steroids in excess of normal physiological requirements (e.g. > 30 days).
- Patient requires revision surgery of a previously implanted total hip replacement or hip fusion to the affected joint.
- Patient has a known sensitivity to device materials.
- Patient is a prisoner.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01257568

Contacts

Contact: Alice Cruz 201-831-5859 alice.cruz@stryker.com
Contact: Christina Hawley, MPH 858-344-9792 christina.hawley@stryker.com

Locations

United States, Michigan

Oakwood Healthcare **Recruiting**
Dearborn, Michigan, United States, 48124
Contact: Kelli Crawford, P.A. 313-429-7977 kcrawford524@yahoo.com
Principal Investigator: Lawrence Morawa, M.D.

United States, Minnesota

St. Cloud Orthopaedics Associates **Active, not recruiting**
Sartell, Minnesota, United States, 56377

United States, New Hampshire

Dartmouth-Hitchcock Medical Center **Withdrawn**
Lebanon, New Hampshire, United States, 03756-0001

United States, Oklahoma

The Orthopedic Center **Recruiting**
Tulsa, Oklahoma, United States, 74104
Contact: Andrea Pope 918-925-3230 apope@toctulsa.com
Principal Investigator: Yogesh Mittal, M.D.

Sponsors and Collaborators

Stryker Orthopaedics

Investigators

Principal Investigator:	Yogesh Mittal, M.D.	The Orthopedic Center
Principal Investigator:	Joseph Nessler, M.D.	St. Cloud Orthopaedic Associates
Principal Investigator:	Lawrence Morawa, M.D.	Oakwood Healthcare System

More Information

No publications provided

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Other Study ID Numbers:	68
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Last Updated:	May 2, 2012
Health Authority:	United States: Institutional Review Board

ClinicalTrials.gov processed this record on June 06, 2012


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