Protocol Registration Receipt
01/15/2014

Multicenter Prospective Cohort Study on Current Treatments of Legg-Calvé-Perthes Disease (IPSG1)

This study is currently recruiting participants.
Verified by Harry Kim, MD, Texas Scottish Rite Hospital for Children, January 2014

Sponsor:	Texas Scottish Rite Hospital for Children
Collaborators:	
Information provided by (Responsible Party):	Harry Kim, MD, Texas Scottish Rite Hospital for Children
ClinicalTrials.gov Identifier:	NCT02040714

Purpose

Legg-Calvé-Perthes disease is a childhood hip disorder which is common enough to be a significant public health problem (affects 1 in 740 boys between ages 0—14), but uncommon enough to have a sufficient number of patients from a single institution to perform a definitive prospective study comparing the results of current treatments. The present study will establish a database of prospectively identified patients with Legg-Calvé-Perthes (LCP) Disease and collect information regarding their presentation, treatment, and outcomes in the course of receiving currently available treatments.

This study seeks to compare the outcomes of current treatments in the management of three age groups (ages 6—8, 8—11, >11) of patients with Perthes disease at two- and five-year followup. For each age group, two to three common treatment regimens currently used by practicing pediatric orthopaedic surgeons will be compared. The intervention a patient receives is determined through physician preference. Physicians pick an intervention for each age group and treat each patient with the same intervention.

Condition	Intervention
Legg Calve Perthes Disease	Procedure/Surgery: osteotomy

Condition	Intervention
	Procedure/Surgery: multiple epiphyseal drilling

Study Type: Observational
Study Design: Cohort, Prospective
Official Title: Multicenter Prospective Cohort Study on Current Treatments of Legg-Calvé-Perthes Disease

Further study details as provided by Harry Kim, MD, Texas Scottish Rite Hospital for Children:

Biospecimen Retention: None Retained
Primary Outcome Measure:

- Sphericity deviation score of the femoral head [Time Frame: 5 years post intervention] [Designated as safety issue: No]

  The primary outcome for each age group will be a quantitative estimate of the sphericity of the femoral head as a measure of femoral head deformity. A more deformed head will be less spherical. Greater deformity leads to an increased risk of arthritis early in life.

Secondary Outcome Measures:

- Perfusion percentage [Time Frame: Just after diagnosis of Perthes disease] [Designated as safety issue: No]

  The perfusion percentage is a measure of the amount of blood flow in the femoral head relative to the volume of the whole head. This measure is calculated from the perfusion MRI images that are collected just prior to the application of the intervention.

Other Pre-specified Outcome Measures:

- Stulberg classification [Time Frame: at 2 years and 5 years post intervention] [Designated as safety issue: No]

  The Stulberg classification is a categorical system used to describe the shape of the femoral head that is traditionally used to evaluate outcomes and arthritis risk for patients with Perthes disease.

Estimated Enrollment: 600
Study Start Date: August 2012
Estimated Study Completion Date: September 2023
Estimated Primary Completion Date: September 2023

Groups/Cohorts	Interventions
Nonoperative management between ages 6-8 The choice of non-osteotomy management without containment or surgical containment would be solely governed by the current practice of the participating surgeons (i.e. the current	

Groups/Cohorts	Interventions
practice of the individual surgeon would be followed within the broad framework of the study).	
Operative containment between age 6-8 in early stage Operative containment treatment (femoral or pelvic osteotomy or Shelf acetabuloplasty) rendered in the early stage of the disease process (stage I)	Procedure/Surgery: osteotomy Surgical procedures that improve femoral head containment Other Names: Femoral osteotomy Shelf osteotomy
Operative containment between age 6-8 in the late stages This arm examines operative containment treatment (femoral or pelvic osteotomy or Shelf acetabuloplasty) rendered in the later stage of the disease process (stage II)	Procedure/Surgery: osteotomy Surgical procedures that improve femoral head containment Other Names: Femoral osteotomy Shelf osteotomy
Nonoperative management between age 8-11 Patients who do not undergo some form of containment surgery because of medical, social, or other reasons will receive no surgical treatment.	
Operative containment with short-term non-weightbearing As per the current standard practice for patients between age 8-11 in developed countries, all patients will undergo some form of containment surgery (pelvic or femoral osteotomy) in order to better "contain" the femoral head underneath the acetabulum. Post-operative treatment will include 6 weeks of non-weight bearing on the operated leg.	Procedure/Surgery: osteotomy Surgical procedures that improve femoral head containment Other Names: Femoral osteotomy Shelf osteotomy
Operative containment with prolonged non-weightbearing As per the current standard practice for patients between age 8-11, all patients will undergo some form of containment surgery (pelvic or femoral osteotomy) in	Procedure/Surgery: osteotomy Surgical procedures that improve femoral head containment Other Names: Femoral osteotomy

Groups/Cohorts	Interventions
order to better "contain" the femoral head underneath the acetabulum. Post-operative treatment will include 6 months of non-weight bearing on the operated leg.	Shelf osteotomy
Multiple epiphyseal drilling for patients over age 11 Patients will receive Multiple drilling and be non weight bearing for 6 months according to the treating physician's preference	Procedure/Surgery: multiple epiphyseal drilling Multiple epiphyseal drilling is a procedure that creates small holes in the femoral head growth plate to increase blood flow into the femoral head.
Multiple epiphyseal drilling and arthrodiastasis Patients will undergo multiple epiphyseal drilling with application of fixator for 3-4 months followed by 8-12 weeks of non-weight bearing after fixator removal.	Procedure/Surgery: multiple epiphyseal drilling Multiple epiphyseal drilling is a procedure that creates small holes in the femoral head growth plate to increase blood flow into the femoral head.
Non-surgical management in over 11 age group Patients will be non-weight bearing and receive physical therapy according to the physician preferences.	

Approximately 40 pediatric orthopaedic surgeons from pediatric centers in the US and other countries have agreed to participate in this database as members of the International Perthes Study Group (IPSG). TSRH will be the lead center. Those who agree to participate will seek IRB approval from their own institutions. Data will be collected prospectively and entered into REDCap (Research Electronic Data Capture), a browser-based research database. PROMIS questionnaires will be completed via an online testing system, the NIH funded Assessment Center.

For the 6—8 age patient group, the surgeons who treat their patients with one of the following three treatment regimens currently used in practice will be asked to participate in the study.

1. Nonoperative management (i.e., without osteotomy);
2. Operative containment treatment (femoral or pelvic osteotomy or Shelf acetabuloplasty) rendered in the early stage of the disease process (stage I); or,
3. Operative containment treatment (femoral or pelvic osteotomy or Shelf acetabuloplasty) rendered in the later stage of the disease process (stage II).

For the 8—11 patient age group, the same treatment regimens will be studied:

1. Nonoperative management (i.e., without osteotomy);

2. Operative containment treatment (femoral or pelvic osteotomy or Shelf acetabuloplasty) with 6 weeks post-operative non-weight bearing; and,
3. Operative containment treatment (femoral or pelvic osteotomy or Shelf acetabuloplasty) with 6 months post-operative non-weight bearing.

For the >11 patient age group, it is known the patients generally have poor prognosis and that the above treatments do not work well. Thus, we will collect prospective data from surgeons who are currently treating their patients with one of the following alternative treatment regimens 5,6:

1. Core decompression or multiple epiphyseal drilling of the necrotic femoral head; or,
2. Hip arthrodiastasis (application of hinged hip distractor) and core decompression/multiple epiphyseal drilling.
3. Non-operative management of symptoms with non-weight bearing

Physicians participating in the study determine their preferred treatment arms for each age group and then enroll patients into arms according to the physicians declared treatment preference for the age group. Patient families have the option to elect nonoperative management even if it is the non-preferred treatment option of the physician.

Information regarding patient characteristics at presentation, physical exam findings, responses to Perthes patient and/or outcomes questionnaires, and results of radiographic and MR imaging studies will be collected. Participants will be assigned a unique study number. A secure web application, REDCap, will be used to capture and store research information including de-identified radiographic and MR images, clinical information, and Perthes patient and/or outcomes questionnaire responses.

All patients willing to complete the PROMIS questionnaires will do so regardless of group, treatment, or stage of the disease. The administration of the instrument is facilitated by the use of an online testing platform, the NIH-funded Assessment Center. Data will be transmitted and stored on a secure and dedicated server for the purpose of this study.

Eligibility

Participants with a recent diagnosis of Perthes disease that are being followed by a participating orthopedic surgeon. Participants are invited to participate during a visit to their treating hospital.

Sampling Method: Non-Probability Sample
Ages Eligible for Study: 6 Years to 16 Years
Genders Eligible for Study: Both

Inclusion Criteria:

- Diagnosed with Legg-Calvé-Perthes disease
- Between age 6-16
- Patients with possible secondary femoral osteonecrosis if over the age of 11 due to trauma or corticosteroid therapy are also eligible.

Exclusion Criteria:

- Patients with previous surgical treatment

Contacts and Locations

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More Information

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