**Clinical Trial ID:**

**NCT00000411**

**Title:**

**Spine Patient Outcomes Research Trial (SPORT): Spinal Stenosis**

**Summary:**

**This study tests the effectiveness of different treatments for the three most commonly diagnosed conditions of the lower backbone (lumbar spine). The purpose is to learn which of two commonly prescribed treatments (surgery and nonsurgical therapy) works better for specific types of low back pain. Low back pain is one of the most widely experienced health problems in the United States and the world. It is the second most frequent condition, after the common cold, for which people see a doctor or lose days from work.**

**In this part of the study, we will treat patients with spinal stenosis (a narrowing of spaces in the backbone that results in pressure on the spinal cord and/or nerve roots) with a type of surgery known as posterior decompressive laminectomy or with nonsurgical methods. This study does not cover the cost of treatment.**

**Detailed Description:**

**Low back pain is considered one of the most widely experienced health problems in the U.S. and the world. It is the second most frequent condition, after the common cold, for which patients see a physician or lose days from work. Estimated costs to those who are severely disabled from low back pain range from $30-70 billion annually. Rates of spinal surgery in the U.S. have increased sharply over time, and researchers have documented 15-fold geographic variation in rates of these surgeries. In many cases, where one lives and who one sees for the condition appear to determine the rates of surgery. Despite these trends, there is little evidence proving the effectiveness of these therapies over non-surgical management.**

**This study will use the National Spine Network to conduct a multicenter, randomized, controlled trial for the three most common diagnostic groups for which spine surgery is performed: lumbar intervertebral disc herniation (IDH), spinal stenosis (SpS), and spinal stenosis secondary to degenerative spondylolisthesis (DS). This arm of the**

**trial will deal with patients from the second diagnostic group. The study will compare the most commonly used standard surgical treatments to the most commonly used standard nonsurgical treatments. We will conduct the study at 12 sites throughout the United States.**

**The primary endpoint of the study will be changes in health-related quality of life as measured by the SF-36 health status questionnaire. Secondary endpoints will include patient satisfaction with treatment, utility for current health in order to estimate quality-adjusted life years (QALYS) as the measure for cost-effectiveness, resource use, and cost.**

**We will follow patients at 6 weeks and 3, 6, 12, and 24 months to determine their health status, function, satisfaction, and health care use. We anticipate that we will enroll and randomly allocate a total of 370 study participants in this arm of the trial. We will track an additional observational cohort to assess health and resource outcomes.**

**Enrollment in the Observational cohort has been completed as of February 2003.**

**We will integrate data from the trial and observational cohorts to formally estimate the cost-effectiveness of surgical versus nonsurgical interventions for IDH, SpS, and DS. The results of this trial will provide, for the first time, scientific evidence as to the relative effectiveness of surgical versus nonsurgical treatment for these three most commonly diagnosed lumbar spine conditions.**

**Eligibility Criteria:**

**Inclusion Criteria:**

- **Duration of Symptoms: 12 or more weeks.**

- **Treatments tried: Nonsteroidal anti-inflammatory medical therapy and physical therapy.**

- **Surgical Screening: Pain in low back, buttocks, or lower extremity that becomes worse with lumbar extension. Must be confirmed by evidence of central or central-lateral compression of the cauda equina by a degenerative lesion of the facet joint, disc, or ligamentum flavum on MRI, computed tomography**

**scans, or**

**myelograms.**

- **Tests: MRI to confirm diagnosis and level(s).**

**Exclusion Criteria:**

- **Previous lumbar spine surgery.**

- **Not a surgical candidate for any of these reasons: Overall health that makes spinal**

**surgery too life-threatening to be an appropriate alternative, patient has improved**

**dramatically with conservative care, or the patient is unable (for any reason) to**

**undergo surgery within 6 months.**

- **Possible pregnancy.**

- **Active malignancy: Patients with a history of any invasive malignancy (except**

**nonmelanoma skin cancer) are ineligible unless they have been treated with curative**

**intent AND have not had any clinical signs or symptoms of the malignancy for at**

**least 5 years.**

**- Current fracture, infection, and/or deformity (greater than 15 degrees of lumbar scoliosis, using Cobb measure technique) of the spine.**

**- Age less than 18 years.**

**- Cauda equina syndrome or progressive neurologic deficit (usually requiring urgent surgery).**

**- Unavailability for followup (planning to move, no telephone, etc.) or inability to complete data surveys.**

**- Symptoms less than 12 weeks.**

**- Patient currently enrolled in any experimental "spine related" study.**

**Gender:**

**All**

**Minimum Age:**

**18 Years**

**Maximum Age:**

**N/A**

**Phase:**

**Phase 4**

**Conditions:**

**- Spinal Stenosis**

**- Low Back Pain**

**Interventions:**

**- Decompressive laminectomy**

**- Non-surgical treatments**

**Locations:**

**- Kaiser Permanente Spine Care Program, Oakland, California**

**- University of California, San Francisco (UCSF), San Francisco, California**

**- Emory University, The Emory Clinic, Decatur, Georgia**

**- Rush-Presbyterian, St. Luke's Medical Center, Chicago, Illinois**

**- Maine Spine & Rehabilitation, Scarborough, Maine**

**- William Beaumont Hospital, Royal Oak, Michigan**

**- Washington University, St. Louis, Missouri**

**- Nebraska Foundation for Spinal Research, Omaha, Nebraska**

**- Dartmouth-Hitchcock Medical Center - Spine Center, Lebanon, New Hampshire**

**- New York University, The Hospital for Joint Diseases, New York, New York**

**- Hospital for Special Surgery, New York, New York**

**- Case Western Reserve University, Cleveland, Ohio**

**- Rothman Institute at Thomas Jefferson University, Philadelphia, Pennsylvania**