Clinical Trial ID:

NCT00000410

Title:

Spine Patient Outcomes Research Trial (SPORT) - Intervertebral Disc Herniation

Summary:

This study tests the effectiveness of different treatments for the three most commonly diagnosed lumbar (lower) spine conditions. The purpose of the study is to learn which of two commonly prescribed treatments (surgery and non-surgical therapy) works better for specific types of low back pain.

In this part of the study, people with lumbar intervertebral disc herniation (damage to the tissue between the bones of the lower spine, or backbone) will receive either discectomy (surgical removal of herniated disc material) or non-surgical treatment. 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 United States and the world. This condition is the second most frequent

condition, after

the common cold, for which people 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 problem appear to determine the rates of

surgery. Despite these trends, there is little evidence proving the effectiveness of

these therapies over non-surgical management.

Overall, the SPORT study is 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 first diagnostic group. The study will compare the most commonly used standard

surgical treatments to the most commonly used standard non-surgical 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 use of health care. In this arm of the trial, we anticipate enrolling and randomly allocating a total of 500 participants. We will track an additional observational cohort to assess health and resource outcomes (1000 participants). 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 non-surgical interventions for IDH, SpS, and DS. On

the basis of the results of this trial we will, for the first time, have scientific evidence as to the relative effectiveness of surgical versus non-surgical treatment for

these three most commonly diagnosed lumbar spine conditions.

Eligibility Criteria:

Inclusion Criteria:

- **Duration of symptoms: 6 or more weeks.**

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

- **Surgical screening: Persistent radicular pain provoked by moderate exercise, sitting, increased abdominal pressure, decreased mobility, list (scoliosis), straight leg raising.**

- **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 which makes spinal surgery too life-threatening to be an appropriate alternative, dramatic improvement with conservative care, or inability (for any reason) to undergo surgery within 6 months.**

- **Possible pregnancy.**

- **Active malignancy: A patient with a history of any invasive malignancy (except non-melanoma skin cancer) is ineligible unless he or she has been treated with a curative intent AND there has been no 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 neurological deficit (usually requiring urgent**

surgery).

- Unavailability for follow-up (planning to move, no telephone, etc.) or inability to

complete data surveys.

- Symptoms less than 6 weeks.

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

Gender:

All

Minimum Age:

18 Years

Maximum Age:

N/A

Phase:

Phase 4

Conditions:

- Herniated Disc

- Low Back Pain

Interventions:

- Diskectomy

- Non-surgical treatments

Locations:

- Kaiser Permanente Spine Care Program, Oakland, California

- University of California, San Francisco, San Francisco, California

- The Emory Clinic, Emory University, 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 Hospital, Philadelphia, Pennsylvania