A multicenter, prospective, randomized study protocol to demonstrate the superiority of a bone-anchored prosthesis for anular closure used in conjunction with limited discectomy to limited discectomy alone for primary lumbar disc herniation

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Abstract

Background: Same-level reherniation and progressive degeneration with disc height loss are main causes of poor outcome after discectomy and may necessitate reoperation. A novel prosthesis for anular closure was developed to address these causes.

Methods: The design of a multicenter, prospective, randomized, post-market superiority trial comparing limited lumbar discectomy augmented with this device (intervention group) with limited lumbar discectomy alone (control group) is presented.

Results: Patients with single-level (L1-S1) posterior or posterolateral disc herniation and radiologic confirmation of neural compression for whom at least six weeks of conservative treatment has failed are eligible. Patients must have posterior disc height ≥5 mm at index level and baseline Oswestry and VAS leg pain scores of ≥40/100. Intraoperatively, subjects meeting anular defect size criteria post-discectomy (4-6 mm tall and 6-10 mm wide) will be randomized to study groups in a 1:1 ratio using centralized, web-based software. A Bayesian statistical approach will be used to enroll 400 to 800 subjects who will be followed for at least 24 months. Two co-primary endpoints will be assessed at 24 months: 1) a composite of leg pain, clinical function, disc height maintenance, and absence of reherniation, reoperation, and device failure; and 2) absence of reherniation based upon independent radiologic analysis.

Conclusions: This type of analysis is becoming increasingly important as governments and health insurers continue to be pressured to spend limited healthcare funding wisely.