

Clinical Trial Evaluating the Safety and Efficacy of Nucleus Pulposus Allograft in Participants With Degenerative Disc Disease

NCT06778447

Status	RECRUITING
Phase	Not Applicable
Sponsor	VIVEX Biologics, Inc.
Enrollment	496 participants

Key Eligibility Criteria

Inclusion (9)

- Age 22 to 85 years old
- Diagnosis of moderate to severe DDD on MRI, Modified Pfirrmann Grade 3-7
- Chronic axial midline low-back pain in the absence of lower extremity motor/sensory/reflex changes with or without referred non-radicular leg pain for at least 6 months prior to screening; unresponsive to at least 3 months of conservative care
- Low-back pain severity score of e 40 to d 90 mm on the VAS
- ODI score of e 40 to d 80
- ... and 4 more (see full listing online)

Exclusion (30)

- Contraindications to the proposed sedation/anesthetic protocol
- Involvement of more than two lumbar discs as evidenced by 3 or more discs with Modified Pfirrmann grade of 3 or greater
- Disc height of less than 4mm for any disc between L1-S1
- Symptomatic vertebral compression fracture
- Previous surgical treatment of the lumbar spine
- ... and 25 more (see full listing online)

Locations (20 total)

Interventional Pain Management Napa Valley Orthopedic Medical Group, Napa, California, United States
Source Healthcare, Santa Monica, California, United States
Premier Spine and Pain Institute, Thornton, Colorado, United States
... and 17 more locations