

A Study to Evaluate the Effectiveness of IDCT (Intradiscal Cell Therapy) in Subjects With One Level, Symptomatic Mild to Moderate Lumbar Degenerative Disc Disease

NCT07254806

Status	RECRUITING
Phase	Phase 3
Sponsor	DiscGenics, Inc.
Enrollment	162 participants

Key Eligibility Criteria

Inclusion (10)

- Has a diagnosis of mild to moderate, symptomatic, single-level degenerative disc disease (DDD) from L3-S1.
- Has a target disc that meets Modified Pfirrmann Grade 3-7.
- Is e18 and d75 years of age, skeletally mature, and has a body mass index (BMI) e18 kg/m2 and d38 kg/m2 at Screening.
- Has been experiencing chronic low back pain for at least 6 months prior to Screening.
- Has had low back pain that is unresponsive to at least 3 months of conservative care (nonoperative treatment) to include at least one non-pharmacological intervention which may include physical therapy, acupuncture, chiropractic manipulation, massage, and at home medically supervised exercise program and two pharmacological interventions which may include NSAIDs, acetaminophen, duloxetine, and/or injectable therapy.

... and 5 more (see full listing online)

Exclusion (47)

- Has low back pain that in the Investigator's opinion is predominately myofascial in nature.
- Has constant, unchanging low back pain that is not improved in any spinal position.
- Has radiculopathy resulting from nerve compression.
- Has non-radicular unilateral or bilateral leg pain with intensity greater than 50% of the intensity of the low-back pain, as measured by VAS.
- Leg pain that is of radicular origin, i.e., due to stimulation of nerve roots or dorsal root ganglion of a spinal nerve by compressive forces.

... and 42 more (see full listing online)

Locations (12 total)

Alabama Clinical Therapeutics, Birmingham, Alabama, United States
Source Healthcare, Santa Monica, California, United States
Injury Care Family Care Research, Boise, Idaho, United States
... and 9 more locations