

Regenn® Therapy System Safety Study

NCT06259409

Status	RECRUITING
Phase	Phase 1
Sponsor	Progenerative Medical, Inc
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (12)

- Subject has provided written informed consent on a form reviewed and approved by the Institutional Review Board for the clinical site.
- The subject is 18 - 80 years old.
- The subject has Spondylolisthesis of Meyerding Grade II or less, or has Degenerative Disc Disease (DDD) accompanied by back pain with or without leg pain at a level between L1 and S1 confirmed by history and radiographic assessment. DDD is determined to be present if one or more of the following are noted:
 - Instability (defined as angulation ≥ 5 degrees and/or translation ≥ 3 mm on flexion/extension radiographs;
 - Osteophyte formation of facet joints or vertebral endplates;
- ... and 7 more (see full listing online)

Exclusion (21)

- Subject is unable or unwilling to provide informed consent or is unable to conform to the study protocol follow-up procedures and visits.
- Subject has a contraindication (including allergic reaction) to antiplatelet/anticoagulant medications, nickel, titanium, bone allograft, or blood transfusion that is not amenable to pretreatment with steroids or/and antihistamines.
- Subject has a history of bleeding diatheses or coagulopathy.
- Subject has concomitant hepatic insufficiency, thrombophlebitis, uremia, systemic lupus erythematosus (SLE), or any autoimmune diseases.
- Subject is receiving dialysis or immunosuppressive therapy.
- ... and 16 more (see full listing online)

Locations (1 total)

The University of Kansas Medical Center, Kansas City, Kansas, United States