

Efficacy and Tolerance Study of B-DYN Versus Conventional Fusion in the Treatment of Lumbar Stenosis on the Degree of Post-operative Functional Incapacity (BDYNCLIN)

NCT04407338

Status	RECRUITING
Phase	Not Applicable
Sponsor	Quanta Medical
Enrollment	216 participants

Key Eligibility Criteria

Inclusion (11)

- Disease related criteria:
- Stenosis on 1, 2 or 3 disc levels (grade B or C or D according to Schizas classification or central stenosis of grade A according to Schizas classification with a lateral stenosis (postero-lateral overhang or disc protrusion)) on MRI (lumbar spine MRI)
- Spondylolisthesis grade 1 or no the upper surgical (treated) level
- Neurological impairment or neurogenic claudication on one or both legs (VAS score ≥ 30)
- Subjects who have failed well-managed medical treatment that has not resulted in long-lasting symptom relief (duration of symptoms ≥ 3 months);
- ... and 6 more (see full listing online)

Exclusion (20)

- Disease related criteria:
- Spondylolisthesis of grade ≥ 1 on the upper surgical (treated) level
- Intervention required on more than 3 disc levels
- Degenerative Scoliosis (Cobb angle $\geq 20^\circ$);
- Stenosis located only on the L5-S1 level
- ... and 15 more (see full listing online)

Locations (2 total)

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