LDGraft in Single Level Anterior Lumbar Interbody Fusion (ALIF)

NCT06462729

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Locate Bio Pty Ltd
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (13)

- Skeletally mature adults e22 and d80 years at the time of surgery
- Willing and able to give written informed consent and comply with study protocol and postoperative management program
- Degenerative disc disease of the lumbosacral spine in one level (L3 to S1) requiring fusion confirmed by patient history and radiographic imaging (CT/MRI/X-rays) with one or more of the following:
- instability (as defined by e3mm translation or e5° angulation);
- osteophyte formation of facet joints or vertebral endplates;

... and 8 more (see full listing online)

Exclusion (22)

- Previous lumbar spine instrumentation (i.e., anterior disc replacement, interspinous device) or a previous interbody fusion procedure in the lumbar spine
- More than one level lumbar spine level requiring fusion
- Three or more contiguous lumbar spine levels requiring decompression (Note: Up to two contiguous levels of decompression is acceptable)
- Known hypersensitivity or allergy to any components of the study treatments inclusive of hypersensitivity or allergy to any BMP-2 type recombinant proteins or peptides.
- Pregnant, planning to become pregnant during the follow-up time period, or breast-feeding women

... and 17 more (see full listing online)

Locations (3 total)

Orthopaedics NorthEast, Fort Wayne, Indiana, United States
Newcastle Private Hospital, Newcastle, New South Wales, Australia
Macquarie University, Sydney, New South Wales, Australia