

Pilot Study of ZetaFuse™ Bone Graft for the Treatment of Cervical Degenerative Disc Disease

NCT05971329

Status	RECRUITING
Phase	Not Applicable
Sponsor	Zetagen Therapeutics, Inc
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (21)

- Age 22 to 75 years (inclusive) at the time of enrollment.
 - Diagnosis of radiculopathy and/or myelopathy of the cervical spine, with pain, paresthesias or paralysis in a specific nerve root distribution C3 through C7, including at least one of the following:
 - Neck and/or arm pain (at least 3 on the 0 - 10 numeric rating scale for pain.
 - Decreased muscle strength of at least one level on the clinical evaluation 0 to 5 scale.
 - Abnormal sensation including hyperesthesia or hypoesthesia. and/or
- ... and 16 more (see full listing online)

Exclusion (27)

- A cervical spinal condition other than symptomatic cervical degenerative disc disease requiring surgical treatment at the involved levels.
 - Documented or diagnosed cervical instability relative to adjacent segments at either level, defined by dynamic (flexion/extension) radiographs showing sagittal plane translation $\gt 3.5$ mm or sagittal plane angulation $\gt 20^\circ$.
 - More than two cervical levels requiring surgical treatment.
 - An immobile or spontaneously fused level adjacent to the levels to be treated.
 - Severe pathology of the facet joints of the involved vertebral bodies.
- ... and 22 more (see full listing online)

Locations (2 total)

Prince of Wales Private Hospital, Randwick, New South Wales, Australia
Prince of Wales Public Hospital, Randwick, New South Wales, Australia