

The Tether™ - Vertebral Body Tethering System Post Approval Study

NCT04505579

Status RECRUITING
Sponsor ZimVie
Enrollment 200 participants

Key Eligibility Criteria

Inclusion (5)

- Diagnosis of progressive idiopathic scoliosis
- Skeletally immature, based on both Risser (<5) and Sanders (<8) assessments
- Major Cobb angle $\geq 30^\circ$ and $\geq 65^\circ$
- Osseous structure dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging
- Failed or intolerant to bracing

Exclusion (6)

- Presence of any systemic infection, local infection, or skin compromise at the surgical site
- Prior spinal surgery at the level(s) to be treated
- Documented poor bone quality, defined as a T-score ≤ -1.5 or less
- Any other medical or surgical condition which would preclude the potential benefit of spinal surgery, such as coagulation disorders, allergies to the implant materials, and patient's unwillingness or inability to cooperate with post-operative care instructions
- Unwillingness, inability, or living situation (e.g. custody arrangements, homelessness, detention) that would preclude ability to return to the study site for follow-up visits as described in protocol and Informed Consent

... and 1 more (see full listing online)

Locations (10 total)

Rady Children's Hospital, San Diego, California, United States
Children's Hospital Colorado, Aurora, Colorado, United States
Nemours Children's Health, Jacksonville, Florida, United States
... and 7 more locations