

Sacroiliac (SI) Joint Transfixing and Fusion: Meaningful Long Term Outcomes With Nevro1

NCT06909292

Status RECRUITING
Sponsor Nevro Corp
Enrollment 180 participants

Key Eligibility Criteria

Inclusion (12)

- Has medical insurance that covers this standard of care procedure and all other anticipated and unanticipated procedure-related care, and all coverage criteria required by insurer are met, which may include but are not limited to:
- Has had low back and/or buttock pain for at least 6 months that is inadequately responsive to non-surgical care
- Has a positive Fortin's test
- Has a diagnosis of SIJ dysfunction (degenerative sacroiliitis or SI disruption) with pain elicited on at least 3 of 5 provocative tests (FABER, Gaenslen, Distraction, Thigh Thrust, Compression).
- At least 75% reduction in pain for the expected duration of two anesthetics (on separate visits each with a different duration of action), and the ability to perform previously painful maneuvers, following an image-guided, contrast-enhanced intra-articular (diagnostic) SIJ injection

... and 7 more (see full listing online)

Exclusion (17)

- Has current severe back pain due to other causes, such as lumbar disc degeneration, lumbar disc herniation, lumbar spondylolisthesis, lumbar spinal stenosis, lumbar facet degeneration, lumbar radicular pain, and lumbar vertebral body fracture
- Has SIJ pain secondary to inflammatory conditions or other known sacroiliac pathology such as: Sacral dysplasia, inflammatory sacroiliitis (e.g., ankylosing spondylitis or other HLA-associated spondylo-arthropathy), tumor, infection, acute fracture, and crystal arthropathy
- Has had a previous SIJ implant placement, including an allograft
- Has had an injection with corticosteroid into the index SIJ within the last 30 days
- Has had a sacral radiofrequency ablation within the last 6 months

... and 12 more (see full listing online)

Locations (5 total)

AIRS Clinic, Lodi, California, United States
Michigan Orthopaedic Surgeons, Southfield, Michigan, United States
Carolinas Pain Institute, Winston-Salem, North Carolina, United States
... and 2 more locations