MagnetOs Flex Matrix Compared to Trinity Elite Mixed With Local Autograft in Patients Undergoing up to Four-level Instrumented Posterolateral Fusion

NCT05037968

Status	RECRUITING
Phase	Not Applicable
Sponsor	Kuros Biosurgery AG
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (4)

- Patient is able to read/be read, understand, and provide written informed consent and has signed the Investigational Review Board (IRB) approved informed consent.
- Male or female patient e 18 years old.
- Patients with leg pain, and/or back pain requiring up to four-level instrumented posterolateral lumbar/thoraco-lumbar fusion (T11 - S1)
- Failed conservative treatment (physical therapy, bed rest, medications, spinal injections, manipulations, or transcutaneous electrical nerve stimulation) for a minimum period of 3 months prior to study enrollment.

Exclusion (16)

- Requires \> four-level fusion or expected to need secondary intervention within one year following surgery.
- Had prior PLF fusion or attempted PLF fusion at the involved levels
- Had previous decompression at the involved levels.
- Women who are or intend to become pregnant within the next 12 months
- To treat conditions in which general bone grafting is not advisable.

... and 11 more (see full listing online)

Locations (7 total)

Hartford Hospital, Hartford, Connecticut, United States
MedStar Health Research Institute, Columbia, Maryland, United States
Michigan Orthopedic Surgeons, Bloomfield Hills, Michigan, United States
... and 4 more locations