A Prospective, Randomized, Single-blind, Controlled, Multi-center Study to Assess the Safety and Performance of MagnetOsTM Compared to Autogenous Bone Graft in Patients Undergoing Hindfoot or Ankle Fusions.

NCT07225751

Status	RECRUITING
Phase	Not Applicable
Sponsor	Kuros Biosurgery AG
Enrollment	126 participants

Key Eligibility Criteria

Inclusion (4)

- Patient is able to read/be read, understand, and provide written informed consent and has signed the IRB approved informed consent.
- Male or female patient e 18 (considered skeletally mature) up to and including 75 years old
- Patients requiring one of the following hindfoot fusion procedures, using surgical technique, necessitating rigid hardware fixation and supplemental bone graft/ substitute: ankle fusion (tibiotalar) subtalar fusion (talocalcaneal), calcaneocuboid fusion, talonavicular fusion, OR double fusion (any combination of any two of the following: subtalar, talonavicular and calcaneocuboid joints).
- Hardware parameters - rigid fixation using screws, plates, staples, nails or a combination.

Exclusion (21)

- Expected to need secondary intervention within one year following surgery.
- Had prior fusion or attempted fusion of the joints to be fused.
- Patient is not ambulatory.
- Surgical technique where bone graft is not expected to be used.
- Conditions at the surgeon's discretion in which general bone grafting is not advisable.

... and 16 more (see full listing online)

Locations (4 total)

Steadman Philippon Research Institute, Vail, Colorado, United States
Hughston Foundation Inc, Columbus, Georgia, United States
Reconstructive Orthopaedic Associates II dba Rothman Orthopaedic Institute, Philadelphia, Pennsylvania, United States
... and 1 more locations