

RISE - Study of the AGN1 LOEP SV Kit in Patients With Vertebral Compression Fractures

NCT04821739

Status	RECRUITING
Phase	Not Applicable
Sponsor	AgNovos Healthcare, LLC
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (14)

- Subject is a male or female 50 years of age or older at time of study treatment.
- Criterion omitted
- Subject has only one (1) acute VCF. Subjects are eligible if they have an asymptomatic healed VCF at any non-target vertebral level.
- This VCF meets all of the following criteria:
- Fracture due to diagnosed or presumed underlying osteoporosis
- ... and 9 more (see full listing online)

Exclusion (26)

- Target VCF is due to underlying or suspected tumor.
- Target VCF is due to high-energy trauma.
- Target VCF is diagnosed as an osteonecrotic fracture.
- Target VCF has segmental kyphosis of $\geq 30^\circ$.
- Target VCF is unstable including split or burst fractures.
- ... and 21 more (see full listing online)

Locations (4 total)

Orthopedic University Hospital Friedrichsheim, Frankfurt am Main, Hesse, Germany
Sana Klinikum Offenbach GmbH, Offenbach, Germany
Hospital Clinico Universitario de Valladolid, Valladolid, Valladolid, Spain
... and 1 more locations