

STAND - Study of the AGN1 LOEP SV Kit Compared to PMMA in Patients With Vertebral Compression Fractures

NCT04835428

Status	RECRUITING
Phase	Not Applicable
Sponsor	AgNovos Healthcare, LLC
Enrollment	408 participants

Key Eligibility Criteria

Inclusion (13)

- Subject is a male or female 50 years of age or older at the time of study treatment.
 - Subject has one (1) or two (2) acute VCF(s). Note that subjects are eligible if they have an asymptomatic, healed VCF(s) at any non-target vertebral level.
 - Each target VCF meets all of the following criteria:
 - Due to diagnosed or presumed underlying osteoporosis
 - T1 to L5 inclusively
- ... and 8 more (see full listing online)

Exclusion (28)

- At least one of the target VCF(s) is unstable, including split or burst fracture.
 - Subject has a bleeding disorder.
 - Subject has an active infection of the spine or surgical site.
 - Subject has a bloodborne infection.
 - At least one of the target VCFs is due to underlying or suspected tumor.
- ... and 23 more (see full listing online)

Locations (19 total)

Alabama Clinical Therapeutics, Birmingham, Alabama, United States
Elite Pain and Spine Institute, Mesa, Arizona, United States
Mayo Clinic, Phoenix, Arizona, United States
... and 16 more locations