

A Clinical Study Evaluating the Safety and Efficacy of the VCFix Spinal System for Treatment of Vertebral Compression Fractures.

NCT07301749

Status	RECRUITING
Phase	Not Applicable
Sponsor	Amber Implants B.V.
Enrollment	103 participants

Key Eligibility Criteria

Inclusion (12)

- Subject is e 21 to d 85 years old.
 - Single vertebral fracture which meets all of the following criteria:
 - Type A fractures from AO spine classification (compression injuries);
 - Vertebral fracture located in the thoracic and lumbar regions of the spine
 - Fracture age \< 6 weeks or fractures with anatomic signs of reducibility (based on radiographic evidence as well as patient history)
- ... and 7 more (see full listing online)

Exclusion (27)

- Neoplasms with posterior involvement and/or presence of a mass within the spinal canal
 - Non-mobile fractures (i.e., fracture is not recent (\>6 weeks), bone marrow edema or fluid or empty cleft are not visible in radiographic imaging, or fracture mode does not allow for fracture reduction in craniocaudal direction).
 - Spondylolisthesis \> Grade 1 at target vertebral body(s)
 - Local kyphotic angle \> 30°
 - Pre-existing vertebral fracture prior to the index fracture
- ... and 22 more (see full listing online)

Locations (3 total)

Centre Hospitalier Métropole de Savoie, Chambéry, France
Wilhelmsburger Krankenhaus Groß-Sand, Hamburg, Germany
Krankenhaus Mechernich, Mechernich, Germany

<https://clinicaltrials.gov/study/NCT07301749>

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