

OSsIRIS Study - A Post-market Clinical Follow-up Investigation.

NCT06156904

Status RECRUITING
Sponsor GreenBone Ortho S.p.A.
Enrollment 135 participants

Key Eligibility Criteria

Inclusion (4)

- Patient is undergoing a standard of care bone grafting with b.Bone for the treatment of surgically created bone defects or bone defects resulting from traumatic injury in the extremities and pelvis according to the approved IFU.
- Male or female patient e 18 years old.
- Patients willing and able to attend the standard of care follow-up visits and procedures.
- Patients who have provided consent to participate in the clinical investigation and to the processing of personal data.

Exclusion (4)

- Patients with any conditions in which b.Bone is not indicated according to the contraindications defined in the IFU of b.Bone
- Patients who are currently enrolled in another clinical investigation/study that would directly interfere with the current clinical investigation, except when the patient is participating in a purely observational study with no associated treatments.
- Woman who is pregnant or breast-feeding.
- Patients who, in the opinion of the Investigator, have an existing condition that could affect their ability to complete patient reported questionnaires or be compliant with the standard of care follow-up visits and examinations for the duration of the clinical investigation.

Locations (4 total)

BG Klinikum Unfallkrankenhaus Berlin, Berlin, Germany
Trauma Surgery Department - University Hospital Regensburg, Regensburg, Germany
Hull University Teaching Hospitals NHS Trust, Hull, United Kingdom
... and 1 more locations