

Zoledronate to Prevent Bone Health Complications in Pediatric Hematopoietic Stem Cell Transplant Survivors

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 5 years to 18 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Patients ≥ 5 and ≤ 18 years old who are preparing for HSCT with a height-for-age corrected DXA Z-score of < -2.0 and admitted to a CCHMC inpatient unit.
- Patients ≥ 5 and ≤ 18 years old recovering from HSCT and who have developed de novo acute or chronic GVHD and are admitted to a CCHMC inpatient unit.

Exclusion Criteria:

- Age < 5 years and > 18 years
- Patients with Fanconi anemia or other radiation-sensitive syndromes with increased malignancy risk
- history of prior bisphosphonate use
- low 25-OH vitamin D levels (< 20 ng/mL)
- active febrile illness
- uncontrolled infection
- Elevated creatinine at the time of enrollment, history or renal failure, or documented low glomerular filtration rate ($GFR \leq 90$)
- Active bone disease including history of abnormal PTH level for any reason, active bone fracture/healing, or primary disorder of bone development or metabolism.
- Women who are pregnant or breast feeding.

Conditions & Interventions

Interventions:

DRUG: Zoledronate

Conditions:

Hematopoietic Stem Cell Transplantation

More Information

Description:

The purpose of this pilot study is to investigate the safety and preliminarily assess efficacy of early intervention with zoledronate in high risk pediatric hematopoietic stem cell transplantation (HSCT) patients to prevent the development of bone disease and fractures and reduce potential pain and suffering.

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Principal Investigator ID:

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IRB Number:

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