

Pharmacokinetics, Efficacy, and Safety of Encaleret in Pediatric Participants With Autosomal Dominant Hypocalcemia Type 1 (ADH1)

NCT07080385

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Calcilytix Therapeutics, Inc., a BridgeBio company
Enrollment	28 participants

Key Eligibility Criteria

Inclusion (4)

- Provide written informed consent (if legally permitted), or have written informed consent from a parent/legal guardian and provide assent (where required and as appropriate per local requirements)
- Have a documented pathogenic or likely pathogenic activating variant, or variant of uncertain significance of the calcium-sensing receptor (CASR), associated with biochemical findings of hypoparathyroidism at screening or a documented history of hypoparathyroidism as manifested by hypocalcemia and intact parathyroid hormone (PTH) <40 picogram per milliliter (pg/mL) (4.2 picomoles per liter $[pmol/L]$)
- Have at least 1 symptom or sign of hypoparathyroidism at screening or a documented history of symptoms or signs of hypoparathyroidism
- Be on ADH1 treatment for at least 6 months before screening for cohorts 1 to 3, or for at least 3 months before screening for cohort 4

Exclusion (7)

- History of thyroid or parathyroid surgery
- History of renal transplantation
- History of cancer (except thyroid cancer, basal cell skin cancer, or squamous cell skin cancer), skeletal malignancies, bone metastases, irradiation (radiotherapy) to the skeleton, chemotherapy with alkylating agents, Paget disease, fibrous dysplasia, chronic osteomyelitis, bone infarcts, benign bone tumors with curettage and bone grafts, retinoblastoma, or Li-Fraumeni syndrome within 5 years before screening
- Received any investigational medicinal product within 30 days or 5 half-lives before Day 1, whichever is longer, or is in follow-up for another interventional clinical study during screening
- Treatment with a strong P-glycoprotein (P-gp) inhibitor within 300 days before screening for amiodarone or within 30 days before screening for any other strong P-gp inhibitor

... and 2 more (see full listing online)

Locations (5 total)

Yale University, New Haven, Connecticut, United States
Nemours Children's Health, Jacksonville, Florida, United States
The Children's Hospital of Philadelphia, Philadelphia, Pennsylvania, United States
... and 2 more locations

<https://clinicaltrials.gov/study/NCT07080385>

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