

Efficacy and Safety of XH02 for the Treatment of Hypoparathyroidism

NCT07197450

Status	RECRUITING
Phase	Early Phase 1
Sponsor	Peking Union Medical College Hospital
Enrollment	6 participants

Key Eligibility Criteria

Inclusion (6)

- Age 18 to 65 years (inclusive), male or female.
- Documented history of post-surgical chronic HP or autoimmune, genetic, or idiopathic HP for at least 26 weeks. Diagnosis of HP is confirmed based on a history of hypocalcemia accompanied by an inappropriately low serum PTH level (below the upper limit of the normal range of the local laboratory). * Note: If a subject lacks documented diagnosis of chronic HP but has exhibited hypocalcemia accompanied by an inappropriately low serum PTH level for at least 26 weeks prior to screening, and is judged by the investigator to meet the diagnostic criteria for chronic HP, they will be considered eligible for this criterion.
- Poorly controlled or intolerant to conventional therapy (calcium and active vitamin D).
- Conventional therapy (including vitamin D or magnesium supplements, if applicable) can be optimized during the screening period to achieve the following target serum levels: 25(OH) Vitamin D level: 10 - 100 ng/mL (25 - 250 nmol/L, inclusive). Blood magnesium level: Within the normal range or slightly below, i.e., ≤ 1.3 mg/dL (≤ 0.53 mmol/L). Albumin-corrected serum calcium (sCa) level: Within the normal range or slightly below
- Body Mass Index (BMI) of 17 to 40 kg/m² (inclusive) at screening.

... and 1 more (see full listing online)

Exclusion (15)

- Impaired PTH response (pseudohypoparathyroidism), characterized by PTH resistance and elevated PTH levels in the presence of hypocalcemia.
- History of allergic predisposition, or known allergy to the investigational drug or polyethylene glycol (PEG)-containing medications.
- Any disease other than HP that may affect calcium metabolism, calcium-phosphate homeostasis, or PTH levels, such as: active hyperthyroidism; Paget's disease of bone; severe hypomagnesemia; type 1 diabetes mellitus or poorly controlled type 2 diabetes (HbA1c $\geq 9\%$; HbA1c results from within 12 weeks prior to screening are acceptable); severe and chronic liver or kidney disease; Cushing's syndrome; multiple myeloma; active pancreatitis; malnutrition; rickets; recent prolonged immobilization; active malignancy (except for low-risk, well-differentiated thyroid cancer or non-melanoma skin cancer); active hyperparathyroidism; history of parathyroid carcinoma within 5 years prior to screening; acromegaly; or multiple endocrine neoplasia syndromes.
- History of vaccination within 4 weeks prior to enrollment, or planned vaccination during the study period.
- Pregnant or lactating women.

... and 10 more (see full listing online)

Locations (1 total)

Peking Union Medical College Hospital, Beijing, China

<https://clinicaltrials.gov/study/NCT07197450>

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