

Parathyroid Allograft for Treatment of Hypoparathyroidism

NCT06961071

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Peter Stock
Enrollment	3 participants

Key Eligibility Criteria

Inclusion (5)

- Subjects age 18 or older.
- Subjects who are able to provide written informed consent and to comply with study procedures.
- Clinical history and laboratory data compatible with HypoPT as defined by hypocalcemia and documented PTH levels either inappropriately normal or below the normal range on two occasions greater than 2 weeks apart and 12 months after surgery, requiring treatment with activated vitamin D (e0.5 mcg calcitrol) and oral calcium (e800mg) daily, or currently on PTH (1-84), PTH (1-34), palopegteriparatide or other recombinant parathyroid hormone replacement injections with ongoing symptomatology due to hypocalcemia and variable degree of biochemical control.
- No history of immunodeficiency (e.g., opportunistic infections) that could be exacerbated by immunosuppression.
- Up to date immunizations per the University of California, San Francisco (UCSF) standard of care for organ transplantation, including influenza, pneumococcal, hepatitis B, and tetanus-diphtheria

Exclusion (24)

- Presence of donor specific anti-HLA antibodies detected by Luminex Single Antigen/specificity bead assay including weakly reactive antibodies that would not be detected by a flow cross match
- Intolerance to any drug that will be used as part of the IS regimen.
- Poorly controlled diabetes with an A1C of $\geq 8\%$.
- Blood Pressure (BP): systolic blood pressure (SBP) ≥ 140 mmHg or DBP ≥ 90 mmHg despite treatment with antihypertensive agents. If the BP is greater than 140/90 chart review and discussion with the patient will be done to establish that BP is in good control.
- For female subjects: Positive pregnancy test, presently breast-feeding, or unwillingness to use effective contraceptive measures for the duration of the study and 4 months after discontinuation. For male subjects: intent to procreate during the duration of the study or within 4 months after discontinuation or unwillingness to use effective measures of contraception. Oral contraceptives, Norplant®, Depo-Provera®, and barrier devices with spermicide are acceptable contraceptive methods; condoms used alone are not acceptable.

... and 19 more (see full listing online)

Locations (1 total)

University of California, San Francisco, San Francisco, California, United States

<https://clinicaltrials.gov/study/NCT06961071>

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