

SCID-X1 Gene Therapy Via Intravenous Lentiviral (IvIv-X1) Injection

NCT03217617

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Shenzhen Geno-Immune Medical Institute
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (10)

- Diagnosis of SCID-X1 based on:
- A proven mutation in the common interleukin-2 receptor gamma chain gene as defined by direct sequencing of patient DNA.
- T-cell immune deficiency defined as one or more of the following: CD3+ autologous T cells \lt 300/uL, or less than 50% of normal value for in vitro mitogen stimulation, or absent proliferation in vitro to antigen stimulation.
- No available HLA identical related donor.
- With severe infections, including but not limited to: pneumonitis; protracted diarrhea requiring total parenteral nutrition; infection with herpes viruses or adenovirus; disseminated BCG infection.

... and 5 more (see full listing online)

Exclusion (8)

- No available molecular diagnosis confirming SCID-X1.
- Existence of an available HLA-identical related donor.
- Diagnosis of active malignant disease other than EBV-associated lymphoproliferative disease.
- Current treatment with any chemotherapeutic agent (becomes eligible if not on treatment for at least 1 month).
- Patients with evidence of infection with HIV-1 or 2.

... and 3 more (see full listing online)

Locations (2 total)

Shenzhen Geno-immune Medical Institute, Shenzhen, Guangdong, China
Guilin Hospital of Chinese Traditional and Western Medicine, Guilin, Guangxi, China