

Treatment of Refractory cGVHD by Donor-derived Treg Cell Injection Combined With Recombinant Human Interleukin-2

NCT06920199

Status	RECRUITING
Phase	Early Phase 1
Sponsor	Shanghai General Hospital, Shanghai Jiao Tong University School of Medicine
Enrollment	18 participants

Key Eligibility Criteria

Inclusion (20)

- Subjects aged 18-70 years old, male or female;
- The subjects had received allo-HSCT, including cord blood transplantation;
- TSubjects with moderate/severe cGVHD that meets the NIH diagnostic criteria (031) for steroid dependence or resistance, meeting one of the following:
- There was no improvement in cGVHD in initial treatment patients treated with $\geq 0.5\text{mg/kg/day}$ or 1 mg/kg/day every other day for at least 4 weeks;
- Steroid dependence: prednisone dose $\geq 0.25\text{ mg/kg/d}$ or $\geq 0.5\text{ mg/kg/qod}$ cGVHD relapse or progression; cGVHD recurred after two attempts to gradually reduce prednisone dose at an interval of at least 8 weeks, with prednisone dose $\geq 0.25\text{ mg/kg/day}$ to be maintained.

... and 15 more (see full listing online)

Exclusion (20)

- Subjects had a recurrence of primary malignant disease before receiving Treg treatment;
- The subjects had persistent, recurrent or delayed aGVHD;
- Continuous use of prednisone $\geq 1\text{ mg/kg/day}$ is required;
- The severity of the subject's cGVHD cannot be assessed by physical examination or laboratory examination;
- overlap syndrome

... and 15 more (see full listing online)

Locations (1 total)

Shanghai General Hospital, Shanghai, China