

Treatment of Pediatric Bronchiolitis Obliterans by Airway Basal Stem Cells

NCT07239895

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| Status | RECRUITING |
| Phase | Early Phase 1 |
| Sponsor | Regend Therapeutics |
| Enrollment | 12 participants |

Key Eligibility Criteria

Inclusion (6)

- Males and females, aged between 28 days and 18 years;
- Diagnosed with bronchiolitis obliterans according to the guidelines;
- Meeting at least one of the following: FEV1 < 55% of predicted value; requiring continuous assisted mechanical ventilation or oxygen therapy;
- None of acute infections within the past four weeks;
- Tolerating bronchoscopy;
- ... and 1 more (see full listing online)

Exclusion (9)

- Subjects with bronchiolitis obliterans syndrome (BOS) who are on a current cGVHD treatment regimen at screening.
- At the time of screening, subject who is positive in each of treponema pallidum antibody (TP-Ab), human immunodeficiency virus (HIV) antibody, hepatitis B surface antigen (HBsAg), hepatitis C virus (HCV) antibody test. Hepatitis B virus carriers with stable current condition can be enrolled. Cured hepatitis C patients with negative result in HCV ribonucleic acid (RNA) test can be enrolled as well.
- Subject who is assessed to have major lung diseases other than BO by investigators at screening or who has other severe systemic diseases within 6 months prior to screening and is considered to be unsuitable for this study by investigators.
- Presence of severe coagulation dysfunction at screening and may compromise the safety of bronchoscopy in the investigator's judgment.
- Subjects requiring long-term maintenance anticoagulant therapy or antiplatelet aggregation therapy, and for whom, in the investigator's assessment, the medication cannot be discontinued within a week prior to cell collection and infusion.
- ... and 4 more (see full listing online)

Locations (1 total)

Shanghai Children's Hospital, School of Medicine, Shanghai Jiao Tong University, Shanghai, China

<https://clinicaltrials.gov/study/NCT07239895>

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