

A Phase 1 Open-Label Study of the Safety of Intravenous Allogeneic Neonatal Mesenchymal Cells (nMSCs) in Young Adult (1A) and Pediatric (1B) Patients With Dilated Cardiomyopathy (DCM)

NCT06464588

Status	RECRUITING
Phase	Phase 1
Sponsor	Emory University
Enrollment	36 participants

Key Eligibility Criteria

Inclusion (10)

- Phase 1A: Age greater than or equal to 18 years and less than 30 years (e18 years, \<30 years).
- Phase 1B: Age greater than or equal to 4 years and less than 18 years (e4 years, \<18 years)
- Subjects must be able to sign their own consent for Phase 1A of the study.
- Diagnosis of dilated cardiomyopathy (DCM) defined as
- Any Congenital Cardiac Malformation with systemic ventricular systolic dysfunction; Idiopathic Cardiomyopathy; Familial/Inherited and/or Genetic Cardiomyopathy; History of Myocarditis; Acquired (Chemotherapy, Iatrogenic, Infection, Rheumatic, Nutritional); Ischemic (e.g. Kawasaki Disease, post-operative); Left ventricular noncompaction; Coronary Artery Disease
- ... and 5 more (see full listing online)

Exclusion (32)

- Listed for heart transplantation (as UNOS status 1A) or hospitalized while waiting for transplant (while on inotropes or with ventricular assist device)
- Cardiovascular surgery of percutaneous intervention to palliate or correct congenital cardiovascular malformations within 3 months of the screening visit. Patients anticipated to undergo corrective heart surgery during the 12 months after entry into Part 1A/1B.
- Previous heart transplant recipient
- Unoperated primary obstructive or severe regurgitant valve (aortic, pulmonary, or tricuspid) disease, or significant systemic ventricular outflow obstruction or aortic arch obstruction.
- Severe mitral valve disease
- ... and 27 more (see full listing online)

Locations (5 total)

Hughes Spalding Children's Hospital, Atlanta, Georgia, United States
Egleston Children's Hospital, Atlanta, Georgia, United States
Emory Children's Center, Atlanta, Georgia, United States
... and 2 more locations