Evaluation of the Safety and Efficacy of BBM-D101 to Treat Patients with Duchenne Muscular Dystrophy

NCT06641895

Status	RECRUITING
Phase	Early Phase 1
Sponsor	Shanghai Jiao Tong University School of Medicine
Enrollment	6 participants

Key Eligibility Criteria

Inclusion (5)

- The legal guardian of the subject fully understands the purpose, nature, methods, and possible risks of the study, and signs a written informed consent form;
- The study includes ambulatory male subjects who are at least 4 years old and less than 8 years old (4 years old d age \< 8 years old) ;
- Genetically confirmed diagnosis of DMD;
- Have at least 1 of the following typical clinical signs or laboratory abnormalities of DMD: proximal muscle weakness, waddling gait, pseudo gastrocnemius hypertrophy, Gower\'s sign, pterygoid scapula;
- Ability to cooperate with motor assessment testing, magnetic resonance imaging (MRI) and muscle biopsy according to the requirements of the study.

Exclusion (6)

- Hepatitis B surface antigen (HBsAg) positive, hepatitis B virus deoxyribonucleic acid (HBV-DNA) e1000U/mL, hepatitis C virus ribonucleic acid (HCV-RNA) positive or human immunodeficiency virus (HIV) positive;
- Receiving antiviral therapy for hepatitis B, hepatitis C, HIV, etc.;
- Left ventricular ejection fraction (LVEF) \<50% or e class III cardiac function defined by New York Heart Association (NYHA);
- With severe or persistent arrhythmias and congenital heart disease.
- The subject\'s preventive treatment/cardiomyopathy treatment changes within 1 month before the start of the study treatment;

... and 1 more (see full listing online)

Locations (1 total)

Shanghai Children's Medical Center Affiliated to Shanghai Jiao Tong University School of Medicine, Shanghai, Shanghai Municipality, China