

Efficacy, Safety, and Tolerability of Zeleciment Basivarsen (DYNE-101) in Participants With Myotonic Dystrophy Type 1

Status: RECRUITING

Eligibility Criteria

Age: 16 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Diagnosis of DM1 confirmed by molecular genetics with trinucleotide repeat size greater than ($\geq$) 100. Historical results from clinical testing are acceptable. * Able to walk 10 meters and complete 5 times sit to stand independently (inserts or supports that don't go above the ankle are allowed). * Body mass index (BMI) less than ($<$) 35 kilograms per meter square (kg/m^2).

Exclusion Criteria:

* A known diagnosis of congenital DM1. * History of major surgical procedure (based on Investigator judgment) within 12 weeks prior to the start of screening, with the exception of implanted pacemaker or defibrillator. * Use of glucagon-like peptide 1 (GLP-1) agonist/incretin medications including semaglutide, dulaglutide, liraglutide, exenatide, or tirzepatide within a period of 5 half-lives of the medication prior to performing screening assessments. Note: Other inclusion and exclusion criteria may apply.

Conditions & Interventions

Interventions:

DRUG: zeleciment basivarsen (DYNE-101), DRUG: Placebo

Conditions:

Myotonic Dystrophy Type 1 (DM1), DM1, Myotonic Dystrophy, Steinert Disease, Steinert

Keywords:

DM1, Myotonic Dystrophy, Myotonic Dystrophy 1, Myotonia, Myotonic Dystrophy Type 1 (DM1), Dystrophy Myotonic, Myotonic Disorders, Steinert Disease, Steinert, Myotonic Muscular Dystrophy, HARMONIA, Dyne Therapeutics, Dyne, DYNE-101, zeleciment basivarsen, z-basivarsen

More Information

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IRB

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