

Study of ATX-01 in Participants With DM1

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 64 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Key

Inclusion Criteria:

* Participants with a documented clinical diagnosis of DM1 (CTG expansion of ≥ 150 repeats in DMPK gene measured in peripheral blood mononuclear cells) * Ambulatory, defined as able to complete a 10-meter walk/run test at screening without the use of assistive devices such as canes, walkers, or orthoses, except for ankle-foot orthoses * Presence for ≥ 3 seconds of grip myotonia as confirmed by a central reader Key

Exclusion Criteria:

* Participants with congenital DM1 * Medical Research Council Muscle Scale score of less than 4 on ankle dorsiflexion or significant tibialis anterior atrophy that prevents a muscle biopsy * Use of mexiletine or other agent for myotonia within 21 days or 5 half-lives, whichever is longer, prior to screening

Conditions & Interventions

Interventions:

DRUG: ATX-01, DRUG: Placebo

Conditions:

Myotonic Dystrophy 1

More Information

Contact(s): Project Manager - clinical@arthexbiotech.com

Principal Investigator:

Phase: PHASE1

IRB

Number:

System ID: NCT06300307

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