

Study of ATX-01 in Participants With DM1

NCT06300307

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| Status | RECRUITING |
| Phase | Phase 1, Phase 2 |
| Sponsor | ARTHEX Biotech S.L. |
| Enrollment | 56 participants |

Key Eligibility Criteria

Inclusion (3)

- 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

Exclusion (3)

- 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

Locations (12 total)

UCLA, Los Angeles, California, United States
University of Florida, Gainesville, Florida, United States
University of Iowa Health Care - Department of Neurology, Iowa City, Iowa, United States
... and 9 more locations

<https://clinicaltrials.gov/study/NCT06300307>

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