

Estab Biomarkers and Clinical Endpoints in Myotonic Dystrophy Type 1 (END-DM1)

NCT03981575

Status RECRUITING
Sponsor Virginia Commonwealth University
Enrollment 700 participants

Key Eligibility Criteria

Inclusion (5)

- Age 18 to 70 (inclusive)
- Competent to provide informed consent
- Clinical diagnosis of DM1 based on research criteria¹ or positive genetic test
- Comment: The clinical research criteria require myotonia, muscle weakness in a characteristic distribution, and history of similar findings in a first degree relative. Genetic testing confirmed the diagnosis of DM1 in > 99% of individuals who satisfied these criteria.²
- • Of the 95 patients undergoing the tibialis anterior muscle biopsy, at least half will have at least moderate weakness of ankle dorsiflexion, defined as MRC score d 4+. This is in order to obtain a muscle tissue sample in a person more severely affected with myotonic dystrophy. Approximately 10 patients at each site will undergo the muscle biopsy.

Exclusion (13)

- Symptomatic renal or liver disease, uncontrolled diabetes or thyroid disorder, or active malignancy other than skin cancer.
- Current alcohol or substance abuse
- Concurrent enrollment in clinical trial for DM1, or participation in trial within 6 months of entry.
- Concurrent pregnancy or planned pregnancy during the course of the study.
- Concurrent medical condition that would, in the opinion of the investigator or clinical evaluator, compromise performance on study measures.

... and 8 more (see full listing online)

Locations (17 total)

University of California, San Diego, La Jolla, California, United States
University of California, Los Angeles, Los Angeles, California, United States
University of Colorado - Denver, Denver, Colorado, United States
... and 14 more locations

<https://clinicaltrials.gov/study/NCT03981575>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at ClinicalTrials.gov. Generated by ClinicalTrialsFinder.org.