Extracellular RNA Biomarkers of Myotonic Dystrophy

NCT05020002

Status	RECRUITING
Sponsor	Massachusetts General Hospital
Enrollment	215 participants

Key Eligibility Criteria

Inclusion (5)

- Subjects with DM1 or DM2 based on genetic testing and/or clinical criteria (some subjects who have positive genetic testing may be asymptomatic, while other subjects who show characteristic clinical features may have declined to have genetic testing done). Control non-DM subjects are unknown to have DM or any other muscular dystrophy by history and may have had no genetic testing.
- Able to provide informed consent or assent for participation in the study.
- Demographic characteristics for single biofluid collection: Males and females age 5 years and older (DM1, DM2, and non-DM).
- Demographic characteristics for repeated measurements: Males and females age 14 years and older with DM1.
- Demographic characteristics for biofluid and muscle biopsy: Males and females, ages 18-65 years.

Exclusion (4)

- Medical history of any of the following. State of immunosuppression; coagulopathy; pre-existing liver or kidney disease; documented HIV positive; documented hepatitis B and/or C positive.
- Medications and other drugs. Use of anti-platelet drugs within 7 days prior to blood draw or biopsy; use of anticoagulants within 60 days prior to blood draw or biopsy; active drug or alcohol use or dependence that, in the opinion of the biopsy surgeon, would interfere with post-procedure wound care.
- Other. Women that are pregnant, or intend to become pregnant, prior to the biopsy; urine pregnancy test that is positive; inability or unwillingness of the subject to give written informed consent.
- Other. Inability or unwillingness of the subject to give written informed consent or assent.

Locations (3 total)

Massachusetts General Hospital, Boston, Massachusetts, United States
Beth Israel Deaconess Medical Center, Boston, Massachusetts, United States
University of Texas Southwestern, Dallas, Texas, United States