Do you or does someone you love have myotonic dystrophy?



Harmony Biosciences is seeking people ages 18-65 with myotonic dystrophy type 1 to enroll in a clinical trial

We will be studying the safety and effectiveness of an investigational medication on excessive daytime sleepiness, fatigue, cognition, and overall burden of disease of myotonic dystrophy type 1



What is required?

Your participation in the trial lasts approximately 4 months.



You'll participate in sleep tests, genetic testing, and an electrocardiogram (ECG).



You'll need to keep a sleep diary for the first week, and a dosing diary once you start treatment.



You will be asked to complete questionnaires related to your symptoms and how you're feeling.



You'll also have physical exams during which blood and urine samples will be collected.

Visit 1

Initial screening and testing to determine eligibility and start your 1-week sleep diary.

Visit 2

Have a physcial exam and daytime sleep test. If you're eligible, you'll begin to take your study medication (once daily in the morning upon wakening) and keep a dosing diary.

Visit 3

You'll have an on-site physical exam and ECG. Before you leave, a heart monitor will be put on and worn for 24 hours.

Visit 4

You'll have an on-site physical exam and ECG.

Visit 5

At your last visit, you'll have an on-site physical exam, daytime sleep test and ECG. If you are eligible and interested, you can enter the long-term safety phase.

SCREENING

DAY 1

DAY 22

DAY 49

DAY 77

Participant's study medication will be the investigational medication or placebo.

Where is the trial planned?



Planned Sites for 2021:



- Irvine, CA
- Aurora, CO
- Gainesville, FL
- Tampa, FL
- Atlanta, GA
- Indianapolis, IN
- Kansas City, KS
- Boston, MA
- Baltimore, MDMinneapolis, MN
- Rochester, NY
- Columbus, OH
- Winston-Salem, NC Philadelphia, PA
- Houston, TX
- Richmond, VA
- Seattle, WA

More to consider



Clinical trials are essential for the development of new treatments. Every new medication and treatment starts with volunteers participating in clinical trials.

- After completion, participants will have the option to enter into the long-term safety extension of the trial to continue to help researchers collect information.
- If you meet the criteria for this part of the trial and you choose to continue, you will receive open-label investigational medication and have periodic check-ins with the trial site to collect information.

LEARN MORE!

Contact clinicaltrials@harmonybiosciences.com to learn more.



More about



We are dedicated to developing and commercializing therapies for patients living with rare neurological disorders who have unmet needs. Learn more at **www.harmonybiosciences.com**.