Friedreich's Ataxia Research

Participants are needed for a a Phase I research study to test an investigational medication in individuals with Friedreich's ataxia.

You May Be Eligible if You:

- 18 years of age or older
- Have genetically confirmed Friedreich's Ataxia
- Are able to traverse 25 feet with or without an assistive device
- Are able to perform basic daily care

Quick Facts

3 clinic visits including
1 Inpatient Stay
of 5 days/4 nights

Total duration up to 58 days

Travel Reimbursement

Compensation for Participating

Clinical research site is located in Eatontown, NJ

Contact Us Today
at (212) 981-2715
or getinvolved@clinilabs.com
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CLIN-1601-101

CTI-1601, a drug being developed by Chondrial Therapeutics, uses a carrier protein to deliver frataxin to the mitochondria in cells. Frataxin is the protein deficient in individuals with Friedreich's ataxia. Your participation in the Phase I study of CTI-1601 will determine safety and tolerability of this investigational medication.

Key Inclusion Criteria

1. Genetically confirmed FRDA diagnosis, homozygous GAA repeat expansion with repeat sizing on diagnostic report.
2. Subject is male or female, 18 years of age or older at screening.
3. mFARS_neuro score ≥ 20 and be able to traverse 25 ft with or without some assistive device (cane, walker, self-propelled wheelchair) and:
    - Sit upright (thighs together, arms crossed) without support on more than 2 sides
    - Transfer with minimal assistance
    - Perform basic daily care with minimal assistance
4. Weight greater than 40 kg

Key Exclusion Criteria

1. Subject requires use of amiodarone
2. Subject used erythropoietin, etravirine, or gamma interferon within 90 days prior to screening
3. Subject with clinically significant arrhythmia on ECG or evidence of predisposition to significant ventricular arrhythmia on ECG, or evidence of active and unstable coronary artery disease
4. Male subject with QTcF > 450 msec or Female subject with QTcF > 470 msec
5. Subject with screening echocardiogram ejection fraction < 45%

There will be additional inclusion and exclusion criteria evaluated at the time of initial screening.

Study Schedule and Time Commitment

This study involves up to 58 days of participation with a total of 3 clinic visits, including a 5 day/4 night stay at a clinical research site in Eatontown, NJ. In the clinical research site during the overnight stay, you will have your own bedroom, a shared accessible bathroom, and activities. CTI-1601 will be given once by injection, and monitoring of response to CTI-1601 will include periodic blood draws.

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