

Research Volunteers Needed

The University of South Florida seeks volunteers to participate in a clinical trial (A Randomized, Double Blind, Controlled, Study to Assess the Safety, Tolerability, and Pharmacokinetics of RT001 Administered to Patients with Friedreich's Ataxia for 28 days; clinicaltrials.gov) to test the safety and tolerability of a an investigational drug given to people with Friedreich's ataxia. The level of the investigational drug will be measured in the blood.

The study involves 10 visits to the research clinic over 6 to 8 weeks with 2 overnight stays of 2 nights each (comprising 6 total clinic visits). Testing at each visit will last about 4 hours or up to 48 hours for timed blood draws on visits with an overnight stay. The visits will be conducted at the USF Morsani Center. You will be reimbursed for your travel expenses.

You will need to follow a diet low in polyunsaturated fatty acids during the study. You will need to keep track of everything you eat each day using an online or paper food diary. The study staff will include a study dietician and diet coach provide more information about the diet (including sample meals, list of foods to eat and avoid, recipes, shopping guide, and frequently asked questions), and answer any questions you have about the diet.

To qualify, you must:

- Have been diagnosed with Friedreich's ataxia
- Homozygous for GAA repeat expansions
- 18-50 years old
- Sufficiently ambulatory to complete a 25 foot timed walk with or without an assistive device

If you would like more information, please contact Dr. Zesiewicz' office at USF: 813-974-5909.

Principal Investigator: Theresa Zesiewicz, MD

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