

Call for Patients with Friedreich's Ataxia Phase II Trial with Varenicline (Chantix®)

Dear FARA Patient Registry Participant:

We are pleased to be able to announce a new clinical research trial recruiting patients with Friedreich's Ataxia in the United States. This is a phase II study looking at the effects of Varenicline (Chantix®) on Friedreich ataxia symptoms, safety, and tolerability. Varenicline is a drug that is approved for smoking cessation and has been suggested to have some symptomatic benefits on ataxia in a few case reports.

We are looking for patients (ambulatory and non-ambulatory) between the ages of 18 and 80 years who have been genetically diagnosed with Friedreich's Ataxia.

To participate, you must Not:

- Have a history of substance abuse, pre-existing schizophrenia, bipolar disorder, have a previous suicide attempt or uncontrolled depression
- Have diabetes or significant heart disease
- Currently be treated with certain antidepressant medications (including Wellbutrin) or nicotine patches
- Currently smoke or have a history of smoking within the past 12 months (Smoking is defined as having smoked any substance even on a single occasion)
- Have been treated with any investigational product within the past 30 days

To participate, you will need:

- Current EKG, echocardiogram, and blood work

About the study:

- Participation in the study is for approximately 8 months and is divided into 2 separate phases
 - Phase one: patients will be treated with study medication or placebo (an inactive pill with no drug in it) for 2.5 months
 - Phase two: all patients will be treated with study medication for 2.5 months
- There are 8 visits to the hospital
 - Patients will be reimbursed for their travel expenses and meals up to \$150 per visit

The study is occurring at the Children's Hospital of Philadelphia and the University of South Florida. For more information about this study and to find out how to take part, please contact one of the following:

Erin Paulsen, BA / Philadelphia, PA / Tel.: (267) 426-9738
Email: Paulsene@email.chop.edu

Lisa Friedman, BA / Philadelphia, PA / Tel.: (267) 426-7538
Email: Friedmanl@email.chop.edu

Kelly Sullivan, MSPH / Tampa, FL / Tel.: (813) 974-5909
Email: kbarber@health.usf.edu

Jennifer Farmer from FARA / Email: Jen.Farmer@curefa.org

In participating in clinical studies, you and other study participants make an important contribution to advancing the treatment of Friedreich's Ataxia.

Thank you for your ongoing support of FARA and clinical research in Friedreich's Ataxia.