

A natural history study to TRACK brain and spinal changes in individuals with Friedreich Ataxia (TRACK-FA)

Status: Recruiting

Eligibility Criteria

Sex: All

Age: 5 Years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Age ≥ 5 years
- Written informed consent provided
- Individuals with FA must have a genetic confirmation of diagnosis and be biallelic for a GAA repeat length > 55 in intron 1 of FXN and/or have a GAA repeat length > 55 in intron 1 of FXN in one allele and another type of mutation that is inferred to cause loss of function in the second FXN allele
- Individuals with FA must have an age of disease onset ≥ 25 years
- Individuals with FA must have a disease duration ≥ 25 years
- Individuals with FA must have a Friedreich Ataxia Rating Scale (FARS) Functional staging score of ≥ 5 and total modified FARS (mFARS) score of ≥ 65 on enrolment

Exclusion Criteria:

- Age < 5 years
- Unable to provide written informed consent
- Magnetic resonance contraindications (e.g. pacemaker or other metallic surgical implants)
- Presence of metallic dental braces
- Pregnancy (ascertained via a question or test as mandated at particular sites)
- Individuals with FA must not have acute or ongoing medical or other conditions that, after discussion between the Site Investigator and steering committee, is deemed to interfere with the conduct and assessments of the study
- Individuals with FA must not have another neurological condition apart from FA
- Individuals with FA must not have other neurologic conditions that, in the opinion of the Site Investigator, would interfere with the conduct and assessments of the study
- Controls must not have a diagnosed psychiatric or neurological condition
- Controls must not have acute or ongoing medical or other conditions that would interfere with the conduct and assessments of the study

Conditions & Interventions

Interventions:

Other: Natural history

Conditions:

Friedreich Ataxia

Keywords:

Neuroimaging, Longitudinal, Biomarkers, Natural history

More Information

Description: TRACK-FA is a multi-site, international, prospective, observational neuroimaging study in Friedreich's Ataxia. The objective is to obtain natural history MRI and MRS data over time in the brain and spinal cord in a large cohort of FRDA patients and healthy control. This will permit validation of neuroimaging biomarkers in FRDA for future clinical trials. In addition to neuroimaging data, the study will collect data from clinical, cognitive and mood assessments as well as blood samples to measure blood markers (frataxin and neurofilament light chain). The present IRB protocol covers only subjects enrolled at the University of Minnesota.

Contact(s): Diane Hutter - hutte019@umn.edu

Principal Investigator: Pierre-Gilles Henry

Phase: NA

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