PROOF HD

Pridopidine Outcome On Function in Huntington Disease (PROOF-HD)

PROOF-HD is a phase 3, randomized, double-blind, placebo-controlled, parallel arm, multicenter study evaluating the efficacy and safety of Pridopidine in patients with Early Stage of Huntington disease (HD).

The purpose of this study is to evaluate the effect of pridopidine on functional capacity, as well as motor and behavioral features of HD in participants with early-stage HD.

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PROOF-HD IS NOW ENROLLING!

FIND A SITE NEAR YOU
www.huntingtonstudygroup.org/proof-hd

HUNTINGTON STUDY GROUP
seeking treatments that make a difference

PARTICIPATING IN NORTH AMERICA
Email inquiries **info@hsglimited.org**
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PARTICIPATING IN EUROPE
Web **https://huntingtonstudygroup.org/proof-hd-study-locations**

WHY IS A STUDY BEING UNDERTAKEN?

The purpose of this study is to evaluate the effect of pridopidine 45 mg twice daily (BID) on functional capacity, as well as on motor and behavioral features in participants with early-stage HD.

In a recently completed clinical study in HD (PRIDE-HD), participants receiving pridopidine dose of 45 mg twice daily, showed maintenance of functional capacity compared to patients receiving placebo, at 52 weeks. This was measured by the Unified Huntington Disease Rating Scale (UHDRS)-Total Functional Capacity (TFC).

The UHDRS-TFC scale is an accepted tool used by clinicians to assess HD disease stage and the level of patient's functionality. The scale is driven by tasks that have high relevance to HD patients and families and assesses the patient's ability to work, to manage finances, to manage a home, to manage oneself, and to live independently at home. TFC is most sensitive to evaluate functionality in early HD patients.

HOW IS THE STUDY ORGANIZED?

The study will consist of a screening period, a double-blind treatment period (Main study) and an Open-label extension (OLE). Participants will undergo screening assessments to determine eligibility, followed by a double-blind treatment period (Main study) between 65 to 78 weeks.

DO I NEED TO PROVIDE CONSENT?

Participants must sign an informed consent prior to beginning the screening process.

WHAT HAPPENS WHEN THE DOUBLE-BLIND TREATMENT PERIOD ENDS?

Eligible participants who complete the double blind treatment period will have the option to enroll into an open-label extension (OLE) period and receive pridopidine (no patients will receive placebo during the OLE).

ARE THERE PRECAUTIONS IN PLACE FOR COVID-19?

Proactive mitigation measures to ensure participant's safety and study integrity during COVID-19 pandemic (or any Public Health Emergency) are included in this study. Virtual visits are incorporated into the protocol to ensure participant safety and minimize the risk of missing data. In addition, in-clinic visits may be converted to a virtual visit, if needed.

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