PRECISE-HD Study Begins Recruitment

The **PRECISE-HD** confirmatory Phase 3 study of pridopidine in Huntington's disease (HD) is now underway. The first US sites are opening for enrollment in **June 2026**, with sites in Europe, UK and Canada to follow on a rolling basis.

400	Up to 75	Up to 3 years	Twice daily
Participants planned	Sites globally	(Including 2 years open label extension stage)	(Oral capsules)

What is PRECISE-HD?

Currently, there are no approved treatments to slow or stop HD from progressing.

PRECISE-HD is a confirmatory Phase 3 clinical study evaluating the efficacy and safety of the investigational medicine pridopidine (taken as an oral capsule twice a day) in people living with HD and is designed to generate the data to further support regulatory evaluation. The study plans to enroll approximately 400 people living with HD, from early to mid-stage disease (defined as Total Functional Capacity (TFC) score of 7-13), and a Total Motor Score (TMS) of ≥20, meaning people who have experienced motor changes or impact on independent functioning. This population is intended to enable the appropriate assessment of any potential effect of the therapy on disease progression in comparison to placebo.

Study Design

STAGE 1	STAGE 2
52 Weeks — Double-Blind	**104 Weeks — Open-Label**
Randomized to receive pridopidine or placebo (1:1)	All eligible participants receive pridopidine for up to 2 further years.

Primary Endpoint

Change from baseline to Week 52 in the combined Unified Huntington's Disease Rating Scale (cUHDRS).

Additional endpoints include function, motor, cognition, speech, and quality of life.

What is Pridopidine?

Pridopidine is an **investigational medicine** (not yet approved). It exerts its effect by activating a protein in the brain called the sigma-1 receptor (S1R) and is often referred to as an S1R agonist. S1R has been shown to play a role in stimulating multiple neuroprotective pathways impaired in neurodegenerative diseases, such as HD. Pridopidine has been shown to improve neuronal cell function and survival via activation of S1R.

- **Approximately 1,600 people** have received pridopidine in clinical studies to date
- **Up to 7 years** of active treatment exposure in some participants
- Generally **well tolerated** in prior HD & ALS studies[1]

Who May Be Eligible?

- Adults with confirmed HD diagnosis
- Early to mid-stage disease (TFC score 7–13)
- Experienced motor changes or impact on functioning

Speak with your neurologist or HD specialist to learn more about eligibility. Local HD patient organizations can also provide guidance and support.

Speech Assessment

PRECISE-HD includes speech as a study endpoint — the first HD study to use objective, technology-based methods to measure speech changes, addressing a historically under-measured aspect of HD.

Learn More

Study registry:
clinicaltrials.gov (NCT07609108)

Study website (coming soon):
www.precisehdtrial.com

Sponsor:
www.prilenia.com | www.ferrer.com

⚠ **Important:** *Pridopidine is an investigational medicine not approved by any regulatory authority. Safety and efficacy have not been established. This update is for informational purposes only and does not constitute medical advice. Speak with your healthcare provider before making any decisions.*

PRECISE-HD / Pridopidine - Questions & Answers for the HD Community

About Pridopidine

What is pridopidine?

Pridopidine is an investigational medicine that activates the sigma-1 receptor (S1R) in the brain, a key neuroprotective pathway. In preclinical HD models, S1R activation improved neuronal cell function and survival. Clinical effects will be evaluated in PRECISE-HD.

Has pridopidine been tested before?

Yes. Approximately 1,600 people have received pridopidine in clinical studies — the majority in HD trials — with some participants on active treatment for up to seven years. It has been generally well tolerated across these studies. Findings from earlier studies informed the PRECISE-HD design.

Is pridopidine approved?

No. Pridopidine is investigational and is not approved for use by any regulatory authority anywhere in the world. Its safety and efficacy have not yet been established.

About the Study

What is PRECISE-HD?

PRECISE-HD (Pridopidine Phase 3 Study to Establish Clinical Impact and Safety in HD is a global confirmatory clinical study evaluating pridopidine (taken as an oral capsule twice a day) in people living with HD.

How large is the study and where is it taking place?

The study plans to enroll approximately 400 participants across up to 75 study sites globally, including in the US, EU, UK and Canada. US sites are opening in June 2026, with other countries following on a rolling basis.

How is the study structured?

The study has two consecutive stages. Stage 1 (52 weeks): participants are randomly assigned to pridopidine or placebo in a double-blind design. Neither participants nor their doctors know which treatment they are receiving. Stage 2 (104 weeks): all eligible participants receive pridopidine in an open-label extension.

Who is Running the Study?

PRECISE-HD is being conducted by **Prilenia** and **Ferrer**, who are co-developing pridopidine. Prilenia is a biopharmaceutical company focused on neurodegenerative disorders. Ferrer is a B Corp-certified international pharmaceutical company with a growing focus on rare neurological disorders.

Study Participation

Who is PRECISE-HD for?

People living with HD from early to mid-stage disease, defined as a Total Functional Capacity (TFC) score of 7–13, and a Total Motor Score (TMS) of ≥20, meaning people who have experienced motor changes or impact on independent functioning. This population enables appropriate assessment of any potential effect on disease progression.

How do I find out if there is a site near me?

Study sites will be listed on www.clinicaltrials.gov (NCT07609108). A dedicated PRECISE-HD website (www.precisehdtrial.com) will launch soon. You may also speak with your neurologist or HD specialist or contact your local HD patient organization for guidance.

Aims of the Study

What is the study trying to show?

It aims to show if pridopidine can slow down the progression of HD in comparison to placebo. The primary end point is evaluation of change from baseline to Week 52 in the combined Unified Huntington's Disease Rating Scale (cUHDRS). Additional endpoints include measures of function, motor, cognition, speech, quality of life, safety, and tolerability.

Why is speech being assessed?

Speech difficulties are common and distressing in HD, significantly impacting quality of life — yet speech has historically been under-measured in clinical studies. PRECISE-HD uses objective, technology-based methods to measure speech changes, addressing this important unmet need.

Next Steps & Contact

How can I find out more or express interest?

Speak with your neurologist or HD specialist. Local HD patient organizations can also provide guidance and support. Participation in any clinical study is completely voluntary. Study information and the site list will be available at:

Learn More

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Study website (coming soon): www.precisehdtrial.com
Sponsor: www.prilenia.com | www.ferrer.com

Not medical advice: Please speak with your healthcare provider for personal guidance. Pridopidine is an investigational medicine that has not been approved by any regulatory authority. Safety and efficacy have not been established. This document is for informational purposes only and does not constitute medical advice. Consult your healthcare provider for treatment decisions or clinical study participation. Local regulations may vary.