

What is a Clinical Trial?

A clinical trial is a research study to evaluate investigational treatments. They are designed to learn if new drugs are safe, tolerable and effective. A clinical trial differs from an observational study in which people are examined over time without receiving any investigational drugs or treatments.

What is the CREST-E Study?

The Huntington Study Group (HSG) is conducting a research study using high-dose, pharmaceutical grade creatine-mono-hydrate in persons 18 years or older who have clinical features of Huntington Disease (HD). CREST-E is designed to measure the effects of creatine-mono-hydrate on the progression of functional decline in HD over 37 months. This research study will also look at the long-term safety, tolerability and effectiveness of treatment with up to 40 g/day of creatine-mono-hydrate, as compared to a placebo, in patients with HD. Additionally, this research will evaluate how a variety of biological processes are affected by the study drug or how they may reflect disease activity or progression. This study will include about 44 research centers around the world and will include 650 subjects for up to 37 months of follow-up each. This research is sponsored by the National Center for Complementary and Alternative Medicine (NCCAM), a division of the National Institute for Health (NIH), and the U.S. Food and Drug Administration (FDA) Orphan Products division.

The 'Who' and 'What' of the CREST-E Study

Who Can Participate?

In order to qualify for the CREST-E trial you must:

- Be at least 18 years old.
- Be able to provide written informed consent.
- Have clinical features of HD and a confirmation by family history or genetic testing.
- Be willing to comply with the study procedures.
- Not be pregnant, lactating or intending to become pregnant.

Further restrictions on participation can be provided to you by your local study research team.

What are the Study Procedures?

If you are interested in participating in the CREST-E study you will first have a visit with the study doctor to determine if you are eligible to participate. This visit will include taking a blood sample, as well as other assessments such as evaluation of your general health, movement and mood.

During the study you will be assigned randomly to receive either active study drug or placebo (looks like study drug but has no active ingredients). You will continue to take

the study drug or placebo for 36 months. Your total participation time will be 37 months. You will have a series of regularly scheduled visits and telephone calls to evaluate your general health, movement and mood throughout the study.

What are the Risks Associated with Participation in CREST-E?

There are mild risks associated with taking blood samples that include pain or bruising at the site where blood is taken. Some of the side effects noted for this study drug are moderate weight gain, gastrointestinal distress such as nausea, upset stomach and diarrhea, and occasionally dehydration or dizziness and there may be unknown risks associated with the use of creatine supplementation. Further detail on these risks is explained in the consent form. Please ask your local study research team if you have any questions or concerns.

What are the Benefits to Me if I Decide to Participate in CREST-E?

It cannot be predicted whether or not there will be any direct benefits to you from your participation in the CREST-E study, however you will be contributing to the growing knowledge about the study drug and Huntington Disease.

How Can I Learn More About CREST-E?

It's easy!

If you think you might want to participate in the CREST-E study you can contact your local study research team.

You can also contact the HSG directly by calling our toll-free number 1 (800) 487 7671 or by visiting us on the web at:

www.Huntington-Study-Group.org.

Your Local Study Coordinator:

[Name]

[Phone]

[E-mail]

About the Huntington Study Group:

The Huntington Study Group (HSG) is an international association of more than 200 clinical investigators, coordinators, scientists and staff from 80 participating hospitals and universities in North America, Europe, Australia and New Zealand.

The HSG is supported by the Huntington's Disease Society of America (New York, NY), the Hereditary Disease Foundation (Santa Monica, CA), CHDI Foundation, Inc. (New York, NY), and the Huntington Society of Canada (Cambridge, Ontario).

Formed in 1993, the HSG strives to advance knowledge about the cause, process and clinical impact of HD in order to develop and test promising therapeutic interventions.

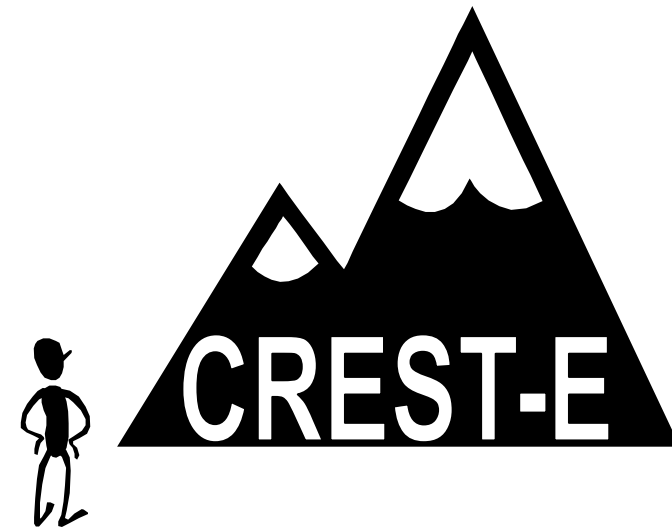
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Create Safety, Tolerability & Efficacy in Huntington's Disease



A Clinical Trial Conducted by the HSG, in conjunction with MGH with sponsorship by NIH/NCCAM and FDA Orphan Products



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