

What is the Huntington Study Group?

The **Huntington Study Group (HSG)** is an international association of more than 250 clinical investigators, coordinators, scientists and staff from over 60 participating hospitals and universities in North America, Europe and Australia.

The HSG is supported by the Huntington's Disease Society of America (New York, NY), the Hereditary Disease Foundation (Santa Monica, CA), HP Therapeutics, 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. The HSG has carried out cooperative therapeutic research since 1993, beginning with the Unified Huntington's Disease Rating Scale (UHDRS) Natural History's database. Since then we have carried out multi-center clinical trials examining the symptomatic and neuroprotective effects of experimental interventions in Huntington's disease. The HSG has partnered with The National Institutes of Health (NIH), the Food and Drug Administration (FDA), pharmaceutical companies, and private foundations to carry out these trials.

Since our inception, we have actively published all of our research efforts in internationally recognized peer-reviewed journals in an effort to make all of our research progress in HD and related disorders available to the public.

For more information about the HSG, including a list of publications generated by the HSG, please visit our website at:

www.Huntington-Study-Group.org

COENZYME Q10 IN HUNTINGTON'S DISEASE (2CARE)

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COENZYME Q₁₀ IN HUNTINGTON'S DISEASE (2CARE)

**A MULTI-CENTER,
RANDOMIZED,
DOUBLE-BLIND,
PLACEBO-
CONTROLLED
CLINICAL TRIAL**

**SUPPORTED BY A
GRANT FROM
THE NATIONAL
INSTITUTE
OF
NEUROLOGICAL
DISORDERS
AND
STROKE
(NINDS)**



What is a clinical trial?

A clinical trial (also called clinical research) is a research study in human volunteers to answer specific health questions. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people and ways to improve health. Clinical trials determine whether experimental treatments or new ways of using known therapies are safe, tolerable and effective under controlled environments.

What is the 2CARE study?

Coenzyme Q10 (CoQ), a naturally occurring substance in the body, is available for purchase as an over-the-counter nutritional supplement. CoQ has been used to treat a variety of human disorders, including those involving the heart and circulatory system, cancer, muscular dystrophy, a muscle coordination disorder called ataxia, and other disorders. The most marked results seem to have occurred in patients with a preexisting inherited deficiency of CoQ, although the studies reporting this information are limited by their not being controlled clinical trials. No serious safety issues have been reported. Recent preliminary studies of CoQ in neurologic disorders such as Parkinson's disease, Amyotrophic Lateral Sclerosis, and Huntington's disease confirm the safety and tolerability of CoQ in daily dosages up to, including, and exceeding the dosage planned for the 2CARE study when used for a short term.

The 2CARE study will be the largest therapeutic clinical trial to date for Huntington's disease, with 608 research subjects with mild to moderate Huntington's disease enrolled at approximately 46 clinical sites in the US, Canada, and Australia for a five-year period.

2CARE Study Information

Who is eligible to participate in 2CARE?

The main entry requirements include:

- Age 16 years or older
- Early (mild to moderate) HD
- Independently walking and fully self-sufficient in activities of daily living (eating, dressing, bathing)
- Identify a caregiver who will maintain control of and supervise the dosing of study medication

Are there risks to me as a research participant?

CoQ could cause some heartburn, headache, fatigue, bloating, or stomach upset. Bloating and stomach upset can usually be avoided by taking CoQ with food. Possible worsening of HD, including an increase in involuntary movements or decline in thinking abilities may occur as a result of taking CoQ. There are some risks when blood is drawn for the blood sample. These risks are further explained in the consent form, and the research investigator or coordinator can also answer any questions.

What study procedures will occur if I agree to participate in 2CARE?

If you would like to participate, you will have screening and baseline visits to determine your eligibility. If eligible, you will begin to take the study drug and will be evaluated at one month, three months, six months and then every six months for a total period of five years. The research center will also contact you by telephone in between your six-month visits to see how you are feeling.

You will be randomly assigned (like the flip of a coin) to receive either the active drug (coenzyme Q10) or a look-alike drug with no active ingredients (placebo).

Study procedures will include a general physical and neurologic exam focused on Huntington's disease, including evaluations of mood and thinking. Blood samples will be taken to assess general health and to measure the amount of CoQ in your blood. An additional blood sample *for research purposes only* will be taken at the beginning of the study and sent to a research lab to confirm that you carry the abnormal HD gene.



How would I benefit by participating in 2CARE?

There is no direct benefit from participating in the 2CARE study. However, you will receive additional evaluations of your condition by a Huntington's disease specialist. You may also contribute to the growing knowledge about Huntington's disease.

How do I find out more information about the 2CARE Study?

If you are interested in learning more about this study, please contact the Huntington Study Group (HSG) at the toll free number:

1 (800) 487-7671

Visit our website at

www.Huntington-Study-Group.org

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2CARE Participating Sites:

Albany Medical College, Albany, NY
Baylor College of Medicine, Houston TX
Boston University, Boston MA
Centre for Movement Disorders, Markham ON
Colorado Neurologic Institute, Englewood CO
Columbia University, New York NY
Duke University, Durham, NC
Emory University, Atlanta GA
Hennepin County Medical Center,
Minneapolis, MN
Hereditary Neurological Disease Centre,
Wichita KS
Indiana University, Indianapolis IN
Institute for Neurodegenerative Disorders,
New Haven CT
Johns Hopkins University, Baltimore MD
London Health Sciences Centre, London ON
Massachusetts General Hospital, Charlestown MA
Mayo Clinic Arizona, Scottsdale AZ
NJ Neuroscience Institute, Edison NJ
NeuroHealth Parkinson's Disease Movement
Disorders Center, Warwick, RI
North Shore/Long Island Jewish Health System,
Manhasset NY
Rush University Medical Center, Chicago IL
The Ohio State University, Columbus OH
UC Davis Medical Center, Sacramento, CA
University of Maryland, Baltimore MD
University of Alabama at Birmingham,
Birmingham AL
University of Alberta, Edmonton AB
University of British Columbia, Vancouver BC
University of Calgary, Calgary AB
University of Cincinnati, Cincinnati OH
University of Florida Movement Disorders Center,
Gainesville FL
University of Iowa, Iowa City IA
University of Kansas, Kansas City KS
University of Miami Miller School of Medicine,
Miami FL
University of Michigan, Ann Arbor MI
University of Pennsylvania, Philadelphia PA
University of Pittsburgh, Pittsburgh PA
University of Rochester, Rochester NY
University of South Florida, Tampa FL
University of Tennessee Health Science Center,
Memphis TN
University of Texas Medical Branch, Galveston TX
University of Texas Southwestern Medical Center,
Dallas TX
University of Virginia, Charlottesville VA
Wake Forest University, Winston Salem NC
Washington University School of Medicine,
St Louis MO
Westmead Hospital, Sydney, Australia