

Announcement of 2CARE Early Study Closure

The National Institute of Neurological Disorders and Stroke (NINDS) stopped its study of coenzyme Q₁₀ for the treatment of Huntington's disease (HD) on July 14, 2014. The study (2CARE), conducted by the Huntington Study Group (HSG), was stopped for futility. The NINDS and the HSG acted on the recommendation of the study's independent Data and Safety Monitoring Board (DSMB). Following the most recent DSMB review of the study data, an interim analysis was conducted that showed that, given the current data, it would be very unlikely (less than a 5 in 100 chance) to see a statistically significant benefit of active treatment (coenzyme Q₁₀, 2400 mg/day) over placebo at the scheduled end of the trial. The DSMB also noted a higher number of deaths in the coenzyme Q₁₀ group (7%) in comparison to the placebo group (4%); most of these deaths appeared to be related to HD, which is a severe, progressive neurological disorder. Although this number may have been due to chance, and was not statistically significant, the DSMB noted it in their decision. Site investigators and coordinators have informed participants of the study closure and have encouraged each participant to schedule a final visit to the clinic.

The 2CARE study enrolled 609 research participants with early Huntington's disease from 48 sites throughout North America and Australia. Participants were randomized to receive either 2400 mg per day of active coenzyme Q₁₀ or matching placebo. The Principal Investigators and the Huntington Study Group are committed to conducting a detailed analysis of the complete data set from the 2CARE study and to disseminating the results through the scientific review process. Even though coenzyme Q₁₀ was not found to be helpful, the study amassed a large amount of longitudinal clinical data which will provide useful information on HD for clinical studies. The study also demonstrated the feasibility of conducting such a large controlled clinical trial in Huntington's disease. The research team is indebted to the participants for their time and dedication to this study.

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