

Huntington Study Group Investigators Announce the Publication of Two Manuscripts in *Archives of Neurology* – “Randomized, Controlled Trial of Ethyl-Eicosapentaenoic Acid in Huntington Disease” and “Communicating Clinical Trial Results to Research Participants”

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The Huntington Study Group (HSG) announces the publication of two papers today in *Archives of Neurology* pertaining to a recently completed, randomized, placebo-controlled trial of an omega 3 fatty acid, ethyl-eicosapentaenoic acid (ethyl-EPA), for people with Huntington disease.

In the first paper, “Randomized Controlled Trial of Ethyl-Eicosapentaenoic Acid in Huntington Disease,” the HSG study investigators report that ethyl-EPA was not beneficial in patients with Huntington disease during the six months of placebo-controlled evaluation. The study involved 316 adults with Huntington disease at forty-one research sites in the United States and Canada. The study’s primary outcome measure was the Total Motor Score 4, a measure of involuntary movements that are seen in individuals with Huntington disease.

After the initial six months of study, all study participants received the study drug, ethyl-EPA, for an additional six months. After twelve months of observation, those that were initially randomized to ethyl-EPA demonstrated improvement on the Total Motor Score 4 compared to those initially randomized to placebo. These potentially beneficial effects require confirmation in longer placebo controlled studies. Ethyl-EPA was safe and well tolerated in the study.

In the second paper, “Communicating Clinical Trial Results to Research Participants,” the study’s investigators and the trial’s sponsor, Amarin Neuroscience Ltd., report on a novel way of providing the trial results to study participants in a timely and personalized manner. Together the investigators and sponsor developed a planned communications effort with three principal elements. The first was a media release from the principal investigators to the Huntington disease community. The second was a telephone call from the study investigators and coordinators to the study participants informing them of the study results. The third was a joint, interactive telephone conference call for the investigators, sponsor, and study participants to communicate study results.

Study participants were surveyed on their source and timing of learning the results and their satisfaction with the communication of the results. Most (73.1%) first learned the study results from the telephone call from site staff. Nearly half (46.3%) learned the results within one day of the initial public release of the results by the sponsor. Surveyed study participants reported high or complete satisfaction with the telephone call from the site (89.3%) and the interactive conference call (82.1%). The study’s investigators and sponsor

conclude, “Surveyed research participants learned of clinical trial results soon after public release and highly valued personalized and accurate communication efforts by the study investigators.”

Currently, despite exposing themselves to known and unknown risks from participating in clinical trials, research volunteers are not routinely informed of trial results. In general, neither federal guidelines nor institutional review boards require disclosure of results at the conclusion of a study. Consequently, many research participants never learn the outcome of studies in which they volunteer. Public investors often are more likely to learn of clinical trial results than research participants as industry sponsors often most inform them of material results.

Dr. Ira Shoulson, the study’s principal investigator commented, “We hope that the commitment that the investigators and sponsor made to communicate the results of the clinical trial in a timely and personalized manner to research participants will set the standard for future clinical trials.”