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Use of a cholinesterase inhibitor in the treatment of VaD: A prospective clinical trial

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Currently there is no approved therapy for the treatment of dementia associated with cerebrovascular disease (VaD). Approximately 600 Patients were selected using NINDS-AIREN criteria in a multi-center, double-blind, placebo control, 24-week period study to show the efficacy of Aricept in this patient population. There were three treatment arms: placebo, 5mg and 10 mg assigned to approximately 200 patients each. The primary efficacy instruments were a performance-based assessment of cognitive function, ADAS-cog and a global assessment scale, CIBIC-Plus. Success was defined as statistically significant improvement from baseline to endpoint in favor of Aricept for both of the primary parameters. Primary efficacy was determined in an FDA-preferred intent-to treat (ITT) population using a last observation carried forward (LOCF) principle.

Change from baseline in ADAS-Cog scores was analyzed via an analysis of covariance model (ANCOVA) developed for the endpoint visit.

CIBIC-Plus was analyzed using Cochran-Mantel-Haenszel (CMH) procedure stratified by centers with MODRIDITS, a uniformly (0,1) distributed function of the rank scores, as the scoring option in the computation of row mean scores at the endpoint visit.

In this poster, we will show the results of the trial and its impact on the public health. To show the robustness of these results we will also present the sensitivity analysis of the ITT-LOCF method and the results of repeated measure analysis comparing the treatment over all the time points to obtain a full clinical picture for the primary efficacy variables.