Neuromuscular Disorders

Volume 21, Issue 6, June 2011, Pages 396-405

Idebenone as a novel, therapeutic approach for Duchenne muscular dystrophy: Results from a 12 month, double-blind, randomized placebo-controlled trial

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https://doi.org/10.1016/j.nmd.2011.02.016

Abstract

Early mortality in Duchenne muscular dystrophy (DMD) is related to cardiac and respiratory complications. A phase IIa double-blind randomized placebo-controlled clinical trial was conducted to investigate the tolerability and efficacy of idebenone therapy in children with DMD. Twenty-one DMD patients (aged 8â€“16Â years) were randomly assigned to daily treatment with 450Â mg idebenone (CatenaÂ®) (nÂ =Â 13) or placebo (nÂ =Â 8) for 12Â months. All subjects completed the study and idebenone was safe and well tolerated. Idebenone treatment resulted in a trend (pÂ =Â 0.067) to increase peak systolic radial strain in the left ventricular inferolateral wall, the region of the heart that is

earliest and most severely affected in DMD. A significant respiratory treatment effect on peak expiratory flow was observed (pÂ =Â 0.039 for PEF and pÂ =Â 0.042 for PEF percent predicted). Limitations of this study were the small sample size, and a skewed age distribution between treatment groups. Data from this study provided the basis for the planning of a confirmatory study.

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Keywords

Duchenne; Muscular dystrophy; Treatment; Idebenone; Cardiac; Cardiomyopathy; Respiratory function

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