

# **A REANALYSIS OF ANEMIA SYMPTOMS IN THE CANADIAN ERYTHROPOIETIN STUDY GROUP (CESG) TRIAL.**

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This study was a reanalysis of the CESG trial, testing the hypothesis that treatment of dialysis patients with Epoetin alfa improves anemia symptoms. The US label for Epoetin alfa (EA) has been recently revised, removing claims that EA reduces the symptoms of anemia. This study applies the same methodology and statistical techniques used to reanalyze the CESG exercise and physical function data that form claims in the revised U.S. label. The CESG was a multi-center, double-blind, randomized, placebo-controlled trial evaluating the effects of IV EA on health-related quality of life in anemic hemodialysis patients. EA was titrated to maintain a Hb of 9.5-11.0 g/dL or 11.5-13.0 g/dL. Analysis was conducted using an intent-to-treat repeated measures mixed model ANOVA using Bonferroni to adjust for multiplicity. Consistent with the analyses that form the current FDA label, results were combined across treated groups.

Table: Hb and Symptom Score Results

Measure	Placebo mean (SE) N = 40		Epoetin alfa mean (SE) N =78		p-value
	Baseline	Month 6	Baseline	Month 6	
<i>Hb (g/dL)</i>	7.2 (1.3)	7.4 (1.7)	7.1 (1.6)	11.0 (2.1)	0.0001
<i>Kidney Disease Questionnaire (KDQ)</i>					
Fatigue Scale	4.5 (0.2)	4.5 (0.2)	4.2 (0.2)	5.2 (0.1)	0.0001
Energy Symptoms	4.1 (0.3)	4.4 (0.3)	3.5 (0.2)	4.8 (0.3)	0.0118
Weakness Symptoms	3.8 (0.3)	4.3 (0.3)	3.4 (0.2)	5.3 (0.2)	0.0110
Shortness of Breath Symptoms	3.9 (0.4)	4.8 (0.5)	4.4 (0.3)	5.5 (0.3)	0.7969

Clinically meaningful improvements were observed in the Epoetin alfa-treated group relative to placebo on KDQ Fatigue, Energy Symptoms and Weakness Symptoms. However, only Fatigue reached statistical significance after applying a conservative Bonferroni-corrected alpha level of 0.0045.