

A REANALYSIS OF THE CANADIAN ERYTHROPOIETIN STUDY GROUP (CESG) PATIENT-REPORTED OUTCOMES (PRO) TRIAL Muirhead N, Keown P, Gitlin M, Mayne TJ, Churchill, DN. UWO, CAN. UBC, CAN. Amgen, USA; Amgen, CAN.

The US label for Epoetin alfa (EPO) has been recently revised. PRO claims are now based exclusively on the results of the CESG trial. CESG was a multi-center, double-blind, randomized, placebo-controlled trial evaluating the effects of IV EPO on health-related quality of life in anemic hemodialysis patients. EPO 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. For the FDA label, results were combined across treated groups.

Measure	Placebo M (SE)		Epoetin alfa M (SE)		p-value
	BL	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>Treadmill (min)</i>	11.9 (0.8)	13.2 (1.1)	13.4 (0.6)	17.2 (0.8)	0.0001
<i>6-Min Walk (m)</i>	446 (18)	440 (22)	447 (12)	486 (18)	0.0498
<i>Sickness Impact Profile (SIP)</i>					
Global	9.6 (1.1)	7.4 (1.0)	12.1 (0.9)	5.5 (0.7)	0.0033
Physical	4.3 (0.8)	4.2 (1.0)	6.4 (0.8)	2.5 (0.4)	0.0015
Ambulation	0.2 (1.7)	9.0 (2.2)	11.7 (1.3)	4.0 (1.0)	0.0077
Body Care & Mvmnt	2.0 (0.6)	2.3 (0.7)	4.4 (0.7)	1.6 (0.3)	0.0068
Home Management	3.1 (2.5)	9.5 (2.4)	16.8 (1.7)	5.7 (1.1)	0.0291
Psychosocial	8.4 (1.5)	4.8 (1.0)	11.0 (1.2)	4.5 (1.0)	0.1558
Communication	1.2 (0.8)	2.3 (0.9)	4.0 (0.9)	2.0 (0.8)	0.0266
Work	23.8(4.6)	30.5 (5.9)	31.8 (3.6)	22.0 (3.6)	0.0021
<i>Kidney Disease Questionnaire (KDQ)</i>					
Physical	4.2 (0.2)	4.6 (0.2)	3.8 (0.1)	5.3 (0.1)	0.0001
Fatigue	4.5 (0.2)	4.5 (0.2)	4.2 (0.2)	5.2 (0.1)	0.0001
Relationships	5.0 (0.2)	5.0 (0.2)	5.0 (0.1)	5.5 (0.1)	0.0037
Frustration	5.1 (0.2)	5.1 (0.2)	4.8 (0.1)	5.3 (0.2)	0.3334
Depression	4.9 (0.2)	4.9 (0.3)	4.7 (0.1)	4.9 (0.2)	0.0114

Comparing to a Bonferroni-corrected alpha level of 0.0045, EPO showed statistically significant improvements in treadmill; SIP Global, Physical & Work; KDQ Physical, Fatigue & Relationships.