

Effect of MV-ONE Nutritional Supplementation on Vitamin D and Epoetin Alfa Dosing

Objective To define the association of MV-ONE® nutritional supplements on hemodialysis patients. MV-ONE® supplemental facts: Cholecalciferol (3000IU), Gamma-tocopherol (300mg), Alpha-Lipoic Acid (800mg). Study was 12 month prospective study versus propensity matched controls on 295 patients

The prospective study was conducted from July 2011 for 12 months in over 15 facilities Only MV-ONE was evaluated and the more concentrated version MV-ONE PLUS® was NOT evaluated in this prospective study.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent disease. All vitamins should be taken under the supervision of a medical professional specializing in the care of patients with renal failure. Consult your physician before starting any supportive multivitamin antioxidant nutraceutical.

Results*

Patient Reported Outcomes (qualitative)

- PROs were not formally recorded

Drug Dosing*

- Patients with high MV-ONE® compliance had lower mean Epogen dose compared to patients with low compliance (7% reduction when adjusted)

Patient reported outcomes were not formally recorded but the ones that were reported were: During the study period, ESA sparing activities were on-going. An additional 7% reduction in EPOGEN dose was reported in the high MV-ONE® compliance group after 12 months.

MV-ONE® Compliance Category	Dose
No MV-ONE® (control)	100%
Compliance Group	98.94%

- MV-ONE® was well tolerated
- An additional **7% reduction** in EPOGEN dose was observed in the high compliance group after 12 months
- Epogen dose reduction was not observed in the low compliance groups
- No significant change in IV hectorol was observed
- No adverse changes in bone and mineral parameters were observed

Conclusions

- MV-ONE® is one of the few nutraceutical supplements evaluated with a prospective study. It has been specifically designed to target inflammation directly (statements not validated by FDA) There were benefits observed consistent with reduced inflammation, namely reduced drug dosing and improved patient well being
- Based on this, MV-ONE® can be used in place of cholecalciferol supplementation with the potential added benefit of reducing inflammation
- MV-ONE® is a non-prescription supplement designed to help reduce inflammation (statements have not been evaluated by the FDA)
- MV-ONE® has been evaluated with a clinical prospective study and shown to confer additional benefits, which may be cost-effective
- MV-ONE PLUS® may have incremental benefits but it has not been evaluated

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*Data on file - see appendix.