

## **Safety and Benefit of Discontinuing Statin Therapy in the Setting of Advanced, Life-limiting Illness: A Randomized Clinical Trial**

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Abstract:

### **Objective:**

To evaluate the safety, clinical, and cost impact of discontinuing statin medications for patients in the palliative care setting.

### **Design and Setting:**

Multi-center (15 sites in USA), parallel group, unblinded, pragmatic clinical trial. Eligible participants had estimated life expectancy between 1 month and 1 year, statin therapy for 3 months or more for primary or secondary prevention of cardiovascular disease, recent deterioration in functional status, and no recent active cardiovascular disease. Analyzed with intention-to-treat analysis.

### **Main Outcome Measure:**

Outcomes included death within 60 days (primary outcome), survival, cardiovascular events, performance status, quality of life, symptoms, number of non-statin medications, and cost savings.

### **Results:**

A total of 381 patients were enrolled (189 were randomized to discontinue statins, 192 continued therapy). Mean age was 74.1 (SD 11.6 years). Of these patients 22% were cognitively impaired and 48.8% had cancer.

There was no significant difference in the proportion of participants in the discontinuation vs. continuation groups who died within 60 days (23.8% vs 20.3%; 90%CI, (-3.5%-10.5%)) and did not meet the non-inferiority end point. Total quality of life was better for the group discontinuing statin therapy (mean McGill QOL score 7.11 vs. 6.85). Cardiovascular events were not significantly different (13 in discontinuation group, 11 in continuation group). Mean cost savings were \$3.37 per day and \$716 per patient.

### **Conclusion:**

Trial suggests that stopping statin medication therapy is safe and may be associated with improved quality of life, use of fewer non-statin medications, and reduction in medication costs.

Comments

**Strengths:** novel study, pragmatic inclusion criteria {"inclusion of patients for who physicians would not be surprised if they died within one year"}, multiple clinical settings, broad range of life-limiting diagnoses included, intention-to-treat analysis, use of validated tools

**Weakness:** primary end point and target sample size were modified midway through study, small amount of patients, no blinding (doctors or patients), difficulty to prognosticate life expectancy, non-inferiority endpoint not reached

**Relevance to Palliative Care:** For patients with limited prognosis, some medication risks or costs may outweigh the benefits, especially when it takes years for the benefits to be achieved, so judicious discontinuation of certain long-term medications should be considered.