

Effects of Fenofibrate 160mg vs. 54mg Conversion on Triglyceride Levels in Patients on Statin Therapy

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ABSTRACT

Purpose:

At least one-third of adults in the United States have high triglycerides and/or low high-density lipoprotein (HDL) cholesterol.¹ Of note, hypertriglyceridemia has become an independent risk factor for cardiovascular disease further highlighting the importance of maintaining levels at goal.^{2,3} Fibrates are commonly used to target elevated triglycerides. The recommended starting dose for patients with primary hypercholesterolemia or mixed hyperlipidemia is 160mg per day. The recommended fenofibrate dose for treatment of hypertriglyceridemia is between 54mg to 160mg per day.⁴ Fenofibrate therapy is commonly initiated at the 160mg per day dose even though the common use of this medication has transformed from monotherapy to adjunct therapy in combination with statins to help patients reach their lipid goals. In such cases 54mg might be adequate to achieve triglyceride goals; therefore, patients are potentially treated with higher doses of fenofibrate than needed possibly increasing their risk of side effects. To our knowledge, no published studies have directly compared the benefit of 54mg versus 160mg of fenofibrate; therefore, there is a need to determine if patients can obtain/maintain adequate lipid levels on the 54mg dose of fenofibrate. The primary objective of this randomized trial is to measure the impact of converting patients on statin therapy from fenofibrate 160mg to 54mg per day compared to patients who continue fenofibrate 160mg per day for triglycerides. Secondary objectives include evaluating effect of the dosage change on low-density lipoprotein (LDL), HDL, alanine aminotransferase (ALT), aspartate aminotransferase (AST), and serum creatinine (SCr), and the potential cost savings associated with prescribing 54mg instead of 160mg.

Methods:

Electronic medical records will be used to identify subjects and gather data on demographics, comorbid conditions, and concomitant lipid lowering therapy. Subjects must be 18 years of age or older, taking a statin and fenofibrate 160mg/day, and have a lipid panel within the past 9 months with most recent triglyceride levels less than 200mg/dL to be included in this study; subjects with a history of pancreatitis, previous fenofibrate 54mg use, and impaired renal function ($\text{CrCl} \leq 50\text{ml/min}$) will be excluded. Subjects will be recruited for enrollment via telephone by the principal investigator (PI), co-principal investigators (Co-PIs), or provider referral after eligibility screening and approval from their primary care physician. Subjects must provide written informed consent and Health Insurance Privacy and Accountability Act (HIPAA) privacy rule authorization prior to participation in this study. Subjects will be randomized to either the intervention arm (conversion to 54mg of fenofibrate) or to the control arm (remain on 160mg of fenofibrate). Subjects in both study arms will have fasting lipid panels, ALT/AST, and SCr evaluated at baseline. All subjects will have repeat labs approximately 8 weeks after enrollment. All subjects will continue to receive standard care based on lipid values. A student t-test will be used to determine if change in triglyceride levels between the study arms is significantly different. The study period will begin approximately October 25, 2010 and run to June 30, 2011.