ClinicalTrials.gov Results Record 220939 (NCT02755818)

Statistical Plan

CCRC: The Independent Effects of Level of Kidney Function and Body Composition on Establishing HDL Cholesterol levels

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Protocol Name:	CCRC: The Independent Effects of Level of Kidney Function and Body Composition on Establishing HDL Cholesterol levels
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Subject: Outcomes/Statistical Plan

HDL levels tend to be low in dialysis patients and triglyceride levels (TG) tend to be high. The levels of HDL are regulated in part by cholesterol ester transfer protein (CETP) and lecithin cholesterol ester transfer protein (LCAT) and TG levels by lipoprotein lipase (LPL). We have planned this study to establish the relationship between estimated glomerular filtration rate (eGFR) and the levels of LCAT, CETP and LPL and their association with HDL levels at different levels of eGFR. Patients with normal renal function with low HDL tend to have low CETP and high LCAT. Patients on dialysis by contrast have low LCAT. We have designed this study to establish the relationship between eGFR, the levels of these enzymes and both HDL and TG levels.

LCAT, CETP and LPL as a function of residual eGFR were to be analyzed by linear regression. This analysis was not done due to our inabilities to recruit willing patients with CKD3b and CKD4 within our recruitment criteria.