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IRB Protocol

Study: The use of complementary and alternative medicine (CAM) in patients with hyperlipidemia

A. Study Purpose and Rationale

It is estimated that greater than one third of all Americans use complementary and alternative medicine (CAM), that is medicine or therapies not prescribed by a physician but use of herbal medications, nutrition supplements, or alternative regimens. The use of such medications has been described in patients with cardiovascular disease, however these surveys have been in select populations. Given the wide and growing use of CAM, this study hopes to illuminate more about what type of patients use CAM and how the use of CAM may impact on achieving treatment goals.

Specifically, this study hopes to follow a group of patients started on a statin for newly diagnosed hyperlipidemia and to prospectively follow them for one year to determine how many patients use CAM in addition to standard lipid lowering therapy. At the end of one year, the number of those individuals who used CAM will be determined by survey. Also studied will be the patient characteristics of those who use CAM such as race, gender, and insurance status, how many were able to reach national lipid guidelines compared to those who did not use CAM, and the attitude towards traditional medications amongst those who used CAM.

B. Study Design and Statistical Analysis

The study will be a prospective observational study. Patients who are newly diagnosed with hyperlipidemia according to national cholesterol guidelines and will be started on statin therapy will be followed for one year. At baseline a survey will be administered to assess baseline characteristics, baseline medication use including use of CAM, and attitudes about the use/efficacy of traditional medicine versus CAM. The medication survey will then be administered again at the end of one year time. Baseline lipid profile will also be drawn to assess baseline LDL prior to statin therapy.

There is no active intervention or randomization of patient to CAM as this is not a study to determine the efficacy of CAM. Rather the patients will segregate themselves according to CAM use. The primary endpoint will be LDL as a continuous variable categorized by if the patient used CAM or did not use CAM.

The study will enroll 1203 patients. This is assuming 1/3 of patient will use CAM, so there will be approximately 401 patients in the CAM group. Assuming those who start a statin and not use CAM will reduce LDL by 17% and those who start a statin and use

CAM will reduce LDL by 21% at one year, this will allow a power of 80% to detect a 4% difference between the groups (assuming a standard deviation of 20%).

C. Study Procedure

All the patients in the trial will be started on a statin therapy as is standard of care for hyperlipidemia. The patients will have venous blood drawn at baseline, 6 months, and at one year to assess for a full lipid profile.

D. Study Drugs

Statins have been well studied, have a well defined safety profile, and are standard of care for hyperlipidemia. If patients are using CAM that is known to be harmful or illegal, they will be told to stop using these medications. No particular CAM will be encouraged or promoted.

E. Study Questionnaires

Study questionnaires will be used at baseline and at one year to assess current and past use of CAM and attitudes about efficacy of CAM vs. traditional medication. The questionnaire about using CAM will be detailed and comprehensively cover herbal medications, over the counter products, and alternative regimens.

F. Study Subjects

Inclusion criteria will be patients with newly diagnosed hyperlipidemia who were previously not on a statin for the prior 12 months. Patients with known hyperlipidemia or already on a statin will not qualify for this study. Also, those with known CAD will be excluded as well. Those with other chronic diseases such as heart failure, chronic renal disease, liver disease, malignancy will also be excluded.

The study seeks to enroll minority patients, especially Hispanic patients. Among Dominican patients presenting to an emergency room in New York, over half were using CAM. However this patient population and its use of CAM has not been well studied or described, despite the fact that CAM plays a large role in medical therapy in this group of patients. One of the goals of the study is to enroll a diverse group of patients to examine their use of CAM.

Subjects will be screened for hyperlipidemia. Family members or cohabitants of those hospitalized for coronary revascularization and those with new clinic visits will be recruited to screen to see if they meet criteria for enrollment. Flyers will be used to recruit patients to screen for hyperlipidemia, as well as via phone calls to household member or family members to those who were recently hospitalized for a coronary revascularization.

F. Potential Risks

The risk involved is minimal as statin is standard of care for hyperlipidemia. Risks of CAM are not well known, and patients who report being on CAM that is known to be harmful or illegal will be informed to stop using such therapies.

G. Potential Benefits

The patient may or may not directly benefit from this study, although they will have their lipids followed while on statin therapy and may have the benefit of improved lipid control. However the main benefit may derive from a societal benefit of further study on the characteristics of patients who use CAM.