

Operations Memo No. 7



VA COOPERATIVE STUDIES PROGRAM # 424

Clinical Outcomes Utilizing Revascularization and Aggressive DruG Evaluation

Date: 7/12/99

From: Pamela Hartigan, Study Statistician, West Haven Coordinating Center

Subj: Lipid determinations

To: Study Personnel

Thru: Trial Leadership

As we have tried to make the study operational in the first week or so, we have determined that there is a problem drawing blood and measuring lipids at baseline. The problem occurs because of the lipid exclusion criteria and also because patients admitted to the hospital with an MI or acute coronary syndrome will not have stable lipid values for a number of weeks.

We now request that you:

1. Make local determination of the patient's lipid profile at study entry.
2. Begin lipid-lowering treatment based on these values.
3. At the first study visit (1 month after randomization) draw, and freeze, blood for the central lab.
4. Continue with all other study procedures including making adjustments to medications based on local determination of lipid profile.

The CHANGE is that the "baseline" determination of the lipid profile done on the blood that is frozen and sent to the core laboratory will be done on a 1 month specimen rather than on one drawn at the time of randomization.

This change in study procedure will allow us to get more stable values for post-MI patients and for cooled-down unstable patients, and will make additional drawing and/or storage of specimens for patients who are not ultimately randomized or a second draw for a patient who is randomized, unnecessary. It is a valid procedure because this study is not a lipid or change in lipid values study but a goal or target lipid value study.