

Operations Memo No. 3



VA COOPERATIVE STUDIES PROGRAM # 424

Clinical Outcomes Utilizing Revascularization and Aggressive DruG Evaluation

Date: May 21, 1999

From: Nancy Morgan, RPh, MBA, Study Research Pharmacist/ VA Cooperative Studies
Program Clinical Research Pharmacy Coordinating Center/Albuquerque, NM

Subj: Provision of Aminophylline to sites as an antidote to Adenoscan

To: Study Personnel

Thru: Trial Leadership

One of the sites has questioned whether the COURAGE study will be providing a supply of aminophylline to each site for use as an antidote to Adenoscan. The answer to this is no.

Despite the fact that the COURAGE Trial protocol follows current practice and published consensus guidelines for the management of patients with coronary heart disease, the COURAGE study chairmen have worked diligently to get as many courtesy drug donations made to this study as possible. They have been very successful both in terms of in the number of agents that are being donated, and in the dollars each site will conserve by avoiding the costs of multiple expensive drugs that would otherwise need to be procured or purchased outside of the COURAGE Trial budget.

Aminophylline can be used as an antidote to pharmacologic stress testing with either adenosine or dipyridamole, the pharmacologic agent used in stress sestamibi scans. Unfortunately, aminophylline is also an inexpensive generic product that no company would donate to the study.

In summary, should the use of aminophylline be required for certain trial patients, its cost to the institution will have been more than offset by the provision of the pharmacologic stress agent (adenoscan), and radio isotope (sestamibi), as well as the other donated therapies each patient will receive during study participation.

Should you have any questions, please do not hesitate to call Karen Potter, RN, BSN, Co-Project Coordinator, CSP #424 at (315) 476-7461, Ext. 2806 (U.S. sites may call 1-800-215-7330) or Paul Casperson, PhD, Co-Project Coordinator, CSP #424 at (210) 617-5300, Ext.3762.