ACRIN 4701 RESCUE: Randomized Evaluation of Patients with Stable Angina Comparing Utilization of Diagnostic Examinations

ELIGIBILITY CLARIFICATION

Dear ACRIN 4701 RESCUE Participating Site Team and Referring Cardiologists:

During a gathering of the cardiologists on the RESCUE trial’s External Advisory Board (EAB) at the American Heart Association meeting, the Board went over the definition for "angina equivalent", per the Inclusion Criteria in Sections 5.1.3 and 5.1.4 of the protocol:

5.1.3 Presentation with symptoms of stable angina (CCS Class I to III) or angina equivalent with or without known CAD;

5.1.4 Planned non-invasive imaging for CAD diagnosis;

We wanted to be sure to clarify that these Inclusion Criteria are defined as the following:

"Any patient with symptoms suggestive of stable known or suspected ischemic heart disease (IHD). This includes new onset stable chest pain or stable pain syndromes."

Anginal equivalent is defined as any symptom or finding or constellation of symptoms or findings that the referring physician feels is concerning for obstructive CAD. Examples of such findings include, but are not exclusive to, chest pain that may not be classic for angina (ie; tightness or burning), shoulder pain, jaw pain, dyspnea, palpitations, nausea, vomiting, diaphoresis.

As mentioned in the RESCUE Trial exclusion criteria patients with acute myocardial infarction (AMI) and acute coronary syndrome (ACS) ie; unstable angina should not be recruited.

If a coordinator is uncertain as to whether a new onset chest pain patient represents stable chest pain or acute coronary syndrome, the coordinator can refer to http://www.mdcalc.com/timi-risk-score-for-uanstemi to calculate a TIMI score. If the TIMI risk score is < 5 and if the enzymes are negative, the patient may be included as they do not have ACS. A link to this website will soon be included on the ACRIN RESCUE webpage.

The above clarification does not constitute a protocol change, although this clarification will be added to the next amendment to the protocol. Essentially, anyone without chest pain at rest (anyone without unstable angina) in whom CAD is suspected fulfills the criteria for entrance into RESCUE.

Sincerely,

Arthur, Pam, Joao

Dr. Arthur Stillman, Dr. Pam Woodard, and Dr. Joao Lima for the ACRIN 4701 RESCUE Trial Team