Randomized Controlled Study of a Rapid “Rule Out” Strategy Using CT Coronary Angiogram Versus Traditional Care for Low-Risk ED Patients with Potential Acute Coronary Syndromes

- Five sites (4 in PA - Tobacco Settlement Fund, 1 outside - ACRIN foundation)
- 1365 subjects, 2:1 randomization CTA (group B) : usual care (group A)
- Primary Aim: estimate the rate of major cardiac events (AMI or cardiac death) within 30 days in group B, who did not have significant CAD by CT
- Secondary Aims
  - Estimate and compare the rates of significant CAD detected within the index visit and subsequent work-up, in participants across the two study groups.
  - Compare hospital length of stay across the two study groups.
  - Compare health care utilization and cost of care in the two study groups during the index hospitalization.
  - Compare cardiac health care utilization and cost of care in the two study arms during 1 year post randomization.
    - Health care utilization components will include cardiac-related lab tests, diagnostic (imaging) tests, interventions, repeat ED visits that for cardiac related problems, and repeat hospitalizations for cardiac pain.
  - Compare the two study groups in terms of the respective rates of major cardiac events (cardiac death, AMI, and revascularization) within 1 year post randomization, experienced by participants who were not found to have CAD at the index visit.
Randomized Controlled Study of a Rapid “Rule Out” Strategy Using CT Coronary Angiogram Versus Traditional Care for Low-Risk ED Patients with Potential Acute Coronary Syndromes

**GROUP A: TRADITIONAL “RULE-OUT” ARM:**
- Disposition per ED study physician
- Serial markers per standard of care
- Banked serum at 3 time points: 0, 90 to 180 minutes, and 6 hours (blood sampling only up until the time of discharge)
- Objective testing per attending (stress test or catheterization) during admission or as outpatient

**GROUP B: CT CORONARY ANGIOGRAPHY “RULE-OUT” ARM:**
- Coronary CTA
- Clinical labs at two times: 0 and 90 to 180 minutes
- Banked serum at 3 time points: 0, 90 to 180 minutes, and 6 hours (blood sampling only up until the time of discharge)

**ELIGIBILITY**
**Low-Risk Patients:** People older than 30 who present to the ED with symptoms consistent with potential ACS, TIMI Risk Scores between 0 and 2, ECG without acute ischemia, and normal cardiac troponin levels.

**POSITIVE TESTS:**
- Admit for further management per guidelines

**NORMAL TESTS:**
- Treat for other diagnoses
- Follow-up as outpatient with established ED protocol

**FOLLOW UP: 30 DAYS AND 1 YEAR**
Telephone contact to assess medical history for resource utilization (e.g., subsequent ED visits, cardiac testing, medication use) and cardiac event rate (including procedures, MI, and death).
• >=64 slice CT scanner able to scan ED patients during fixed hours
• CTA protocol performed per local routine
• ACC/AHA level III trained readers
• Post-processing software allowing quantification of stenoses and calcium scoring
• All stenoses must be quantified to at least include
  – <50%
  – 50-69%
  – >70%
• Defined usual care protocol for r/o ACS
Protocol approved by ACRIN IRB in May 2009
- now v. 3 approved by ACRIN and site IRBs
- Enrollment began in June 2009 at HUP, PPMC
- PSU MC (Hershey) and Pitt added 12/2009
- Wake Forest added 4/2010

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Accrual as of September 7, 2010
ACRIN-PA 4005: Recruitment Issues and Blood

- Pittsburgh
  - Staff changes, reimbursement
  - Protocol modifications may help somewhat
- Hershey
  - Reimbursement a concern, but has not turned out to be an issue
- Penn Presbyterian Medical Center
  - Heart rate control (more later)
- Blood draws - HUP and PPMC only (428 possible as of Sept 7)
  - 268 with time 0
  - 236 with 90-180 min
  - 140 with 6 hours (many patients discharged or admitted prior to 6 hours)
17% of patients randomized to CT did not have CT
- 37% at PPMC
  - Heart rate control (single source 64 slice scanner)
  - Equipment broken or otherwise not available
- Other sites 11-17%
- Overall reasons
  - Heart rate control 22%
  - Medical reason 20%
    - Physician decision to rule out another diagnosis (+d-dimer)
  - Equipment failure 9%
  - Other - contrast allergy, pt too big for scanner, no IV access, etc.
- Study quality
  - 2% uninterpretable
  - 6% interpretable but uninterpretable segments in main or first order
  - 13% interpretable but some segments poor quality
  - 6% of pts in Trad Care arm end up having CTs
ACRIN-PA 4005: Followup and AEs

- 569 pts reached 30-day followup
  - 83% have had followup form submitted
    - 97% of those have been contacted, 3% determined lost to followup (will try again up to end of study)
    - 17% not yet contacted or determined lost to followup
  - 44 pts have reached 1 year followup
    - 50% have had followup form submitted - 100% contact rate
    - 50% not yet contacted or determined lost to followup
- 7 AEs in CT group (don’t track in Trad Care group)
  - 4 IV infiltrates
  - 1 contrast reaction
  - 1 heart block from Ca channel blocker
  - 1 excess radiation due to rescan (?AE)
- Radiation - tracking in monthly report
  - Feedback to 1 site has resulted in change in imaging protocol
ACRIN-PA 4005: Radiation

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Radiation Dose Histogram

![Radiation Dose Histogram](image-url)
ACRIN-PA 4005: Outstanding issues

- Adjudication committee
  - Will review all deaths and MIs in both arms identified at initial visit (after negative evaluation), 30 day or 1 year followup
  - Determine whether death was cardiac related and if AMI did occur
  - Frank Peacock and Robert Hendel have agreed to serve

- Recruitment
  - Current trend - we won’t complete recruitment by July 2011
  - PA money will run out Jan 2012
  - Reimbursement front-loaded (initial and 3 month visits)
    - Sites have to manage budget to pay salaries for 1 year f/u
  - PA wants published report by March 2012