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Emergency Medicine Research and Outcomes Consortium

EMROC Relax-AHF2 —Final Newsletter

RELAX AHF 2: Final Thoughts

Thanks for all of the hard work on RELAX AHF 2. We know there was a flurry of activity at the end for the PIs and coordinators to finalize data entry, minimize lost to follow-up, and sign the eCRFs. As a result of your diligence the database is now locked and primary and secondary analyses are underway. Its unclear exactly when the primary results will be presented. The top line results have been released to the public and indicate RELAX-AHF2 was a neutral study. We do not have any further details regarding primary and secondary endpoints, though we should hear a lot more in the next month as the primary and secondary results become available.

EMROC Relax-AHF2 —Final Newsletter

Ongoing EMROC studies

1) REPORT HF—closed to enrollment

(International Registry to assess medical Practice with longitudinal observation for Treatment of HF)

Steering Committee Member: Sean Collins, MD, MSc

Sponsor: Novartis Pharmaceuticals

This study has met its enrollment goals . The EMROC sites accounted for a significant proportion of patients, especially after study re-start in January 2017. This undoubtedly was one of the reasons for rapid accrual and finishing ahead of schedule. REPORT HF enrolled nearly 19,000 patients world wide, 1356 patients in the US, with 918 (5% overall, 68% in the US) patients enrolled at EMROC sites. This is outstanding! Continued follow-up will be crucial over the next 2-3 years.

2) High Sensitivity cTnT Rules Out Acute Cardiac Insufficiency Trial (TACIT)

PI: Peter Pang, MD, MS

Co-Investigators: Sean Collins, MD, MSc, Phillip Levy, MD, MPH, and Greg Fermann, MD

Sponsor: Investigator Initiated Trial from Roche Diagnostics

Hospitalization for acute heart failure (AHF) results in a high rate of post-discharge mortality and re-admissions, as well as high financial costs. Reducing 30-day re-admissions after AHF hospitalization is a major national quality goal intended to both improve patient outcomes and reduce costs. Such efforts however, often focus on patients at highest risk, presuming that these patients represent the greatest potential opportunity. Another approach involves safely preventing hospitalizations when a patient presents to the ED for their initial evaluation. Retrospective analysis suggests patients with low hsTnT level are at very low risk for adverse events. With this pilot study, we will generate the necessary and sufficient pilot data to inform the design of a definitive trial to test whether identification of low risk AHF patients with negative serial hsTnT in the ED may be safely discharged home or observed briefly in observation status. **Update**: Enrollment has resumed. Vanderbilt has met its quota of 125 patients and is closed to enrollment. Indiana (57), Wayne State (107) and Cincinnati(60) continue to enroll. There are currently 352 patients enrolled out of 500 total. We hope to complete 75% enrollment by Aug 1, 2017 with the goal to complete patient enrollment by Feb 1, 2018.

3) EMROC Registry

PI's:Peter Pang, MD, MS, Phillip Levy, MD, MPH, Greg Fermann, MD, Jennifer Martindale, MD and Sean Collins, MD

Collecting ED data about patients with AHF and sharing it with others supports the development of new diagnostic, therapeutic and disposition decision making pathways. Further, biomarker exploration may lead to safe, innovative, and effective new medicines and diagnostics to address healthcare needs, improve medical care, and promote and improve public health. The objective of the EMROC registry is to create a repository of ED patients who present in the exacerbation phase of their disease. **Update:** We have enrolled over 1050 patients at our centers to create this comprehensive ED-based registry. Data cleaning is now underway for all patients enrolled through March 16, 2017. All sites should have received an invitation from Cathy Jenkins to Box to find their data queries. Those who have not received an invite please let us know ASAP. After this data has been cleaned, our goal is to externally test the STRATIFY rule. We will likely need over 1000 patients with clean data to do so. The next step would then be a multi-center implementation trial.

4) Get with the Guidelines in ED Patients with Heart Failure (GUIDED HF)

PI's: Sean Collins, MD, MSc, Phil Levy, MD, MPH, Peter Pang, MD, MS, Gregory Fermann, MD

Get with the Guidelines in Emergency Department Patients with Heart Failure (GUIDED HF) is a multicenter, randomized, 1:1 trial comparing 1) standardized ED discharge vs. 2) a tailored discharge plan implementing get with the guidelines heart failure (GWTG:HF) recommendations via an ED coordinator led study team in patients with AHF discharged from the ED.
The trial will enroll 700 patients discharged from the ED or observation unit with AHF, as diagnosed by the treating physician. Entry criteria will permit enrollment of ED patients: 1) in whom AHF is diagnosed, 2) for whom ED physicians intend to discharge from the ED or after a period of observation of less than 24 hours, 3) who are low-risk and will not have difficulties complying with the protocol due to psychiatric disease, dementia, or proximity to the enrolling institution, making the study team home visit problematic. The primary outcome is time to 90-day ED revisit, hospital admission or CV death, and secondary outcomes include HF quality of life, HF knowledge and patient satisfaction. **Update:** We have enrolled 227 patients thus far. Our interim analysis will occur once 350 patients have been enrolled. We hope to conduct this in the fall/winter of 2017.