EM RESEARCH CURRENT STUDIES

ATACH-II: H-27236: Hypothesis-Intensive SBP reduction using IV nicardipine with treatment initiated within 4.5 hours of ICH onset and continued for the next 24 hours reduces the likelihood of death or disability at Day 90 compared with standard SBP reduction using IV nicardipine. Randomization-Intensive SBP control (<140) vs. Standard SBP control (140-180). PI: Dr. Sergot

CROFAB: H-34502: Purpose-To learn if people recover better after being bitten by a copperhead snake when given the anti-venom Crofab. Randomization-Crofab vs. Placebo with rescue treatment. PI: Dr. Greene

INC Research: H-34220: Purpose-To determine non-inferiority in early clinical response rate of IV solithromycin compared to IV moxifloxacin in adult patients with CABP. Randomization-Solithromycin vs. Moxifloxacin. PI: Dr. Gonzalez

PEARL: H-34862: Purpose-To validate the clinical performance of the TnI, CKMB, and myoglobin assays on the Alere Triage Cardiac Panel and the Alere Triage ProfiLER SOB Panel as an aid in the diagnosis of MI. Device study on blood drawn from ED subjects. PI: Dr. Peacock

POINT: H-28352: Purpose-To determine whether clopidogrel 75mg/day (after a loading dose of 600 mg) is effective in preventing major ischemic vascular events at 90 days when subjects are randomized within 12 hours of time last known free of new ischemic symptoms in patients receiving aspirin 50-325 mg/day. Randomization-Clopidogrel vs. Placebo. PI: Dr. Sergot

PORTOLA: H-32861: Hypothesis-Extended prophylaxis for VTE using oral Betrixaban for 35 days is more effective for VTE prophylaxis through 35 days after randomization in acute medically ill patients than 10 days of parenteral enoxaparin and displays a superior risk benefit profile. Randomization-Betrixaban vs. Placebo. PI: Dr. Gonzalez

PREVENCIO: H-34358: Purpose-To collect blood so the sponsor can validate the optimal biomarker panel for rule-in and rule-out of ACS as well as determine short-term patient prognosis. Blood collection study from ED subjects. PI: Dr. Peacock

SHIRE: H-33538: Purpose-To compare the efficacy of icatibant with placebo in the treatment of ACE-I induced angioedema based on the time to meeting discharge criteria. Randomization-Icatibant vs. Placebo. PI: Dr. Greene

SOCRATES: H-33786: Hypothesis-Ticagrelor monotherapy is superior to ASA monotherapy in reducing the incidence of major vascular events as measured by the composite of stroke, MI and death in patients with acute ischemic stroke or TIA. Randomization-Ticagrelor or placebo vs. ASA or placebo (double-blind, double-dummy). PI: Dr. Deal

TRINITY: H-33978: Purpose-To validate the clinical performance of the Meritas Troponin I test for the quantitative determination of cTnI for use as an aid in the diagnosis of MI in subjects presenting to an ED
with symptoms suggestive of ACS and/or MI. Device study on blood drawn from ED subjects. PI: Dr. Peacock

TRUE: H-31784: Purpose-To evaluate the effect of a continuous IV Ularitide infusion on the clinical status and Cardiovascular mortality of patients with ADHF. Randomization-Ularitide vs. Placebo. PI: Dr. Kuo

EM RESEARCH UPCOMING STUDIES

CEPHEID: H-35247: Purpose- The objective of this multi-site prospective study is to establish the performance characteristics of the Xpert Flu+RSV Xpress Assay for rapid identification and differentiation of Flu A, Flu B and RSV in CLIA Waived (CW) intended user environments (for example: emergency rooms, physicians’ offices, outpatient clinics and/or retail pharmacy) PI: Dr. Rafique

GENENTECH: H-35508: Purpose- The purpose of this study is to find out what effects, good and/or bad, MHAA4549A, an investigational drug developed by Genentech Inc. (‘the Sponsor’), has while treating
symptoms of influenza. The investigational drug will be given in combination with oseltamivir (Tamiflu®), which is a medicine that is a currently accepted treatment for influenza. PI: Dr. Gonzalez

INSYS: H-35135: Purpose- To evaluate the efficacy of SUBSYS relative to standard of care parenteral analgesia in overall pain relief in ED patients with acute pain; To evaluate the safety and tolerability of SUBSYS relative to standard of care parenteral analgesia in overall pain relief in ED patients with acute pain. Interventional Drug Study. PI: Dr. Rafique

INTREPID: H-34710: Purpose- NNZ-2566 is being developed by Neuren Pharmaceuticals Limited as a treatment for TBI. The purpose of this study is primarily to assess the safety of the new investigational drug, NNZ-2566, in human patients with TBI. An additional purpose of the study is to find out if NNZ-2566 improves abnormal brain electrical activity and reduces or prevents brain seizures in the acute stage of TBI. The longer term goal of this study is to provide doctors with a safe and effective drug with which to treat TBI patients. Randomization-NNZ-2566 vs. placebo (2:1). PI: Dr. Peacock/Dr. Rafique

IO: H-32771: Purpose-To determine the efficacy and safety of pressure-limited power injection of contrast medium through the IO route via the EZ IO catheter for CT exams. Observational study. PI: Dr. Gonzalez

LUPUS: H-35416: Purpose- This Study is multi-site collection of healthy control samples to complete a series of control samples for which the case specimens have been previously obtained and stored in a sample bank. Blood Collection study from ED subjects. PI: Dr. Peacock

PRADAXA: H-33556: Purpose-To assess the clinical characteristics of the GI and GU bleeding events in patients with non-valvular AF taking dabigatran who present to EDs for management of such events. Retrospective chart review. PI: Dr. Wu

PRONTO-II: H-34515: Purpose-To evaluate dyspnea improvement in acute heart failure patients receiving intravenous infusion of clevidipine in comparison to placebo or standard of care. Randomization-Clevidipine vs. placebo vs. standard of care. PI: Dr. Kuo

SEIMEN’S: H-H-35395: Purpose- This protocol will enroll emergency department subjects prospectively under informed consent in order to establish a repository of samples that will be used to validate performance claims for one or more Siemens Troponin (TnI) diagnostic devices. Blood collection study from ED patients. PI: Dr. Peacock

SHINE: To determine the efficacy of tight glucose control to a target range of 80-130 mg/dl with IV insulin infusion in hyperglycemic acute ischemic stroke patients within 12 hours of symptom onset as measured by mRS at 90 days after stroke. PI: Dr. Sergot