

DEPARTMENT OF EMERGENCY MEDICINE

Research Activity Report – Funded Research August 2014

- **Actively Enrolling**

1. **Neurological Emergency Treat Trials (NETT) – KCHC/SUNY – HUB**

(Spokes: Lincoln and Maimonides)

NIH-NINDS 1U10NS080377-01

Barsan(PI)

2012-2017

Neurological Emergency Treatment Trials (NETT). An infrastructure grant to support multiple treatment trials (Phase 3 Clinical Studies) from NINDS. The Hub consists of Kings County Hospital and SUNY-Downstate Medical Center with spokes of Lincoln Hospital and Maimonides Medical Center.

2. **NIH-NINDS 5U01NS062835**

Johnston (PI)

2012-2017

Platelet-Oriented Inhibition in New TIA and Minor Ischemic Stroke (POINT)

The primary goal of the POINT trial is to determine if the drug clopidogrel combined with aspirin is effective in preventing ischemic stroke and myocardial infarction (heart attack).

3. **NIH-NINDS 5U01NS062835**

Johnston (PI)

2012-2017

Stroke Hyperglycemia Insulin Network Effort (SHINE) Trial

The primary goal of the SHINE trial is to determine if aggressive glycemic control in the setting of acute stroke decreases stroke-related morbidity.

4. **NIH-NINDS 5NETT028749-3**

Wright (PI)

2012-2017

Protect III Trial – Enrollment Suspended

The primary goal of the Protect III trial is to determine if Intravenous Progesterone improves the outcome of patients suffering a Traumatic Brain Injury

5. **NIH-NINDS 1U01NS062091**

Qureshi (PI)

2010 – 2015

Antihypertensive Treatment of Acute Cerebral Hemorrhage (ATACH-II)

The goal of this randomized, phase III clinical trial is to determine whether conventional or aggressive blood pressure lowering in acute intracerebral hemorrhage is more effective therapy.

6. **ClinicalTrials.gov Identifier: NCT01919801 (Kimuar PI)**

2013-2015

Blinded Safety & Efficacy Placebo Controlled Study of Icatibant for Angiotensin Converting Enzyme Inhibitor Angioedema (CAMEO Study)

This study is being conducted to compare the safety and efficacy of icatibant with placebo in the treatment for Angiotensin-Converting Enzyme Inhibitor (ACE-I)-Induced Angioedema in Adults.

Sponsor: Shire Human Genetic Therapies, Inc.

7. **ClinicalTrials.gov Identifier: NCT01546532 (Metra Marco - PI)**

2013-2016

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A multicenter, randomized, double-blind, placebo controlled phase III study to evaluate the efficacy, safety and tolerability of Serelaxin when added to standard therapy in acute heart failure patients (Relax-2 Study)

Efficacy, Safety and Tolerability of Serelaxin When Added to Standard Therapy in AHF

Sponsor: Novartis

- **Plan Enrolling September 2014**

1. ClinicalTrials.gov Identifier: NCT01661634 (O'Connor & Peacock – PI's) 2014 – Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Ularitide (Urodilatin) Intravenous Infusion in Patients Suffering From Acute Decompensated Heart Failure [TRUE-AHF Study]

To evaluate the effect of a continuous intravenous (IV) ularitide infusion on the clinical status and cardiovascular mortality of patients with ADHF.

Sponsor: Cardiorentis Ltd.

2. ClinicalTrials.gov Identifier: NCT01966601 (Soergel – PI) 2014 – A Randomized, Double-Blind, Placebo-Controlled, Dose Ranging Study to Explore the Efficacy of TRV027 in Patients Hospitalized for Acute Decompensated Heart Failure (Blast Study)

To evaluate the overall safety and efficacy of TRV027 when administered in addition to standard of care (SOC) on mortality, morbidity, dyspnea, and length of stay in patients hospitalized with Acute Decompensated Heart Failure (ADHF).

Sponsor: Travena, Inc.

STUDIES IN DEVELOPMENT

1. ClinicalTrials.gov Identifier: NCT02088957 (UCB) 2014- A Randomized, Open-label, Multicenter, Parallel-group, Exploratory Study to Evaluate the Efficacy of Intravenous Brivaracetam and Intravenous Phenytoin in Subjects Experiencing Nonconvulsive Electrographic Seizures

The primary objective of this study is to compare the efficacy of Brivaracetam and Phenytoin, both administered intravenously, in adult subjects experiencing nonconvulsive electrographic seizures.

Sponsor - UCB

2. ClinicalTrials.gov Identifier: NCT02104947 (Pollack – PI) 2014 – A Phase III Case Series Clinical Study of the Reversal of the Anticoagulant Effects of Dabigatran by Intravenous Administration of 5.0g Idarucizumab (BI 655075) in Patients Treated With Dabigatran Etxilate Who Have Uncontrolled Bleeding or Require Emergency Surgery or Procedures.

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Evaluate the reversal of the anticoagulant effects of dabigatran by IV administration of 5.0g idarucizumab in patients treated with dabigatran etexilate who have uncontrolled bleeding or require emergency surgery or procedures.

Sponsor: Boehringer Ingelheim

3. ClinicalTrials.gov Identifier: NCT02011685 (Ogedegbe-PI) 2014-Practice-Based Trial of Home BP Telemonitoring Among Minority Stroke Survivors

The primary objective is to assess the effects of HBPTM+NCM versus HBPTM alone on change in systolic blood pressure (SBP) from baseline to 12 months and stroke recurrence at 24 months in minority stroke patients with uncontrolled hypertension. The secondary objective is to compare the cost-effectiveness of the two interventions at 12- and 24-months.

Sponsors: New York University School of Medicine

National Institute of Neurological Disorders and Stroke (NINDS)

4. PROSPECTIVE, OPEN-LABEL STUDY OF ANDEXANET ALFA IN PATIENTS RECEIVING A FACTOR XA INHIBITOR WHO HAVE ACUTE MAJOR BLEEDING

To evaluate the hemostatic efficacy of andexanet in spontaneous or traumatically-induced major bleeding in patients who have reduced fXa activity from use of a fXa inhibitor.

Sponsor: Portola Pharmaceuticals, Inc.