January 2020 Updates on ED Clinical Trials

There is a lot going on in our Emergency Department! And with the expansion in hospitals, we welcome Adventist, Tuality, and CMH to the team, and hope the other sites will consider future research opportunities. Thank you for your continued support to make these trials successful. Each, and every one of you, are needed to move the needle of science forward as we provide high-quality healthcare. **–Bory Kea, Director of Clinical Trials**

ACTIVE ED STUDIES

Heart Failure Pro BNP

Evaluating a new pro-BNP assay in patients with heart failure (for diagnosis and severity assessment).

- PI: Kea; Coordinator: Joy Kim
- Inclusion criteria: >22 yo and <50 yo and >74yo, male with SOB and/or edema; enrollment within 11hrs of presentation
- Exclusion: Trauma, on dialysis, prisoner, homelessness, and prior enrollment
- Enrollment-to-date: **56**
- Site Goal: 100 (enrollment period through February 2020)

Digital Capillary Refill with HydraSense

Using a novel device (Hydrasense) to compare manual vs digital capillary refill: currently enrolling in patients 6mo-65yo.

- PI: Sheridan; Coordinator: Nancy Le
- Enrollment-to-date: **184**
- Goal: 600

This study requires NO work or input from RNs or MDs. The study team will work around staff with any patients they enroll to make sure and prioritize your time with them over the study.

HydraSense for Sepsis

A novel device for distal perfusion: currently enrolling in patients 6mo-65yo with fever, sepsis, and ESI 2-3.

- PI: Sheridan; Coordinator: Nancy Le
- Enrollment-to-date: **15**
- Enrollment Goal: 100

Solace

Wearable technology for physiologic monitoring of adolescent suicidality: enrolls adolescents presenting with suicidality with goal of developing objective/physiologic markers that correlate with escalating suicidality.

- PI: Sheridan; Coordinator: Nancy Le

- Enrollment-to-date: **67**
- Enrollment Goal: 200 across the pediatric ER and inpatient adolescent psychiatric unit at Unity

UPCOMING ED STUDIES

BOOST- 3 Brain Oxygen Optimization in Severe TBI Phase-3 Trial (a SIREN Network study)

BOOST 3 is a trial being run through the nationwide SIREN Network. OHSU is an "award hub", and 4 of our OHSU network sites will also be participating in this trial (OSU, Duke, University of Utah, and University of Rochester Medical Center). A total of 45 sites will be enrolling patients throughout the duration of this trial. BOOST 3 will operate under EFIC (Exception from Informed Consent) rules, and is currently conducting public disclosure activities, and final team training.

- PI: Daya, Coordinator: Jenny Cook
- Registered with ClinicalTrials.gov: NCT03754114
- Status: Pre-study preparations
- Enrollment Launch: ~January 2020

ICECAP- Influence of Cooling Duration on Efficacy in Cardiac Arrest Patients (a SIREN Network study)

OHSU will enroll patients locally at Portland Adventist and OHSU. Additionally, OHSU is anticipating that 5-6 of its network partners will also be conducting ICECAP.

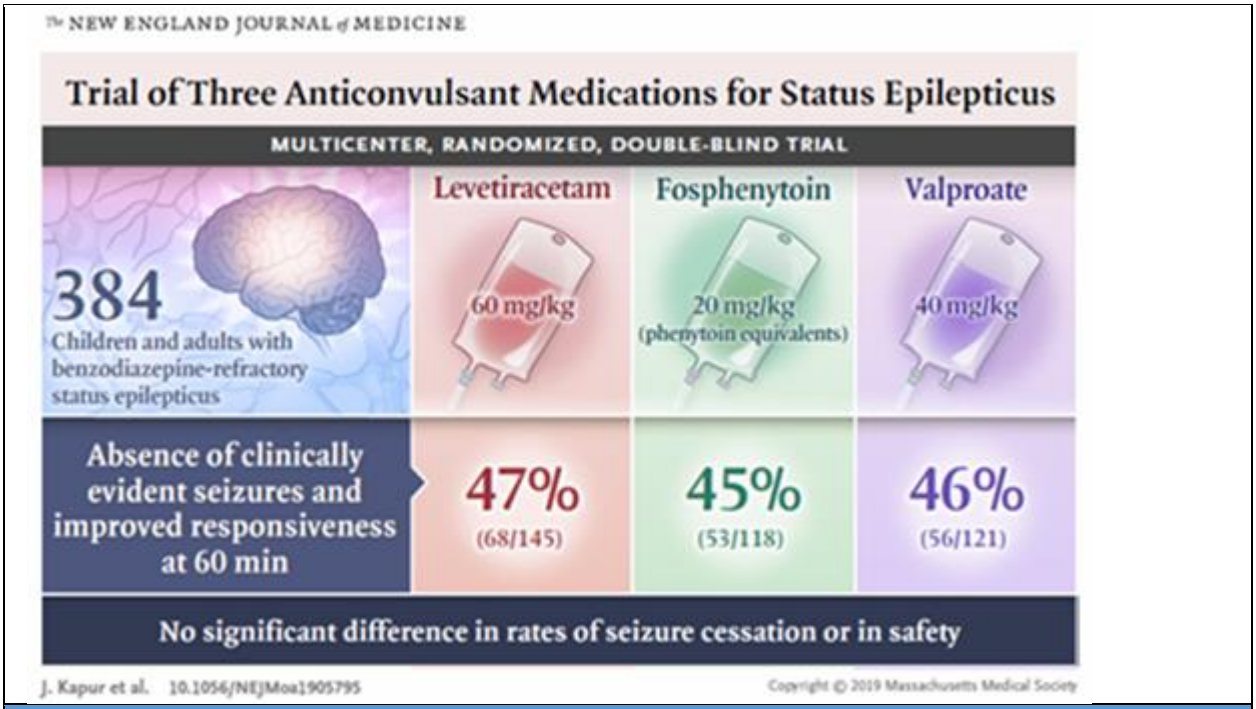
- PI: Daya
- Status: Pre-study Preparation
- Launch: Spring 2020

CLOSED ED STUDIES

ESETT- Established Status Epilepticus Treatment Trial (a NETT Network study)

The ESETT Trial was conducted at OHSU from November 2015-June 2018, and OHSU enrolled 9 subjects locally, and 2 at our satellite site in Utah.

- Findings from this trial were published on Nov. 28, 2019 in the New England Journal of Medicine, below is a summary graphic © NJEM. https://nett.umich.edu/sites/default/files/docs/nejm-esett_primary.pdf



ICU-ED SEPSIS STUDIES

VICTAS

Giving *vitamin C, thiamine, and steroids* in patients with **septic shock** or **respiratory failure from sepsis** (ventilator, BiPAP, HFNC dependent)

- PI: Khan, Kea
- Site Enrollment: **23**
- Status: Closed to enrollment
- Total Enrollment Goal of 500 reached across 43 sites

IVY

Multi-center observational study evaluating the efficacy of influenza vaccines among critically ill and hospitalized patients.

- PI: Khan
- Site Enrollment: 58
- Site Goal: 100 until March 2020 (5 per week)
- Total Enrollment Goal: 700 until March 2020

CLOVERS (a PETAL Network study)

Multi-center randomized controlled trial using *liberal fluid strategy vs early vasopressor strategy* in patients with Septic Shock (sepsis + hypotension)

- PI: Khan, Co-I: Kea
- Site Enrollment: 104
- Site Goal: 146 April 2021 (1 per week)
- Total Enrollment Goal: 2200 until April 2021

Questions for ICU team

- Contact our study team Smartweb à Last Name à PRISM (#11912) (8am to 9pm) Site PI Akram Khan (khana@ohsu.edu) pager à 15351 or text/cell 503-449-4314 (24 hours).