



Small



Madara

SPOTLIGHT ON CLINICAL RESEARCH

*Pediatric Concussions, Music Therapy for Preemies,
Heart Failure & Exercise Tolerance, Hip Fracture Medication*

Heather Madara

Clinical Research Coordinator

Roy S. Small, M.D.

Medical Director of Clinical Research

Penn Medicine Lancaster General Health Research Institute

Editor's note: *This is the fifth in a series of articles from the Penn Medicine Lancaster General Health Research Institute that describes ongoing research studies, with a focus on those actively enrolling patients. Other active studies have been described in previous issues of this Journal.*^{1,2,3,4}

Physicians who wish to refer patients for any of the studies mentioned below are encouraged to contact the Penn Medicine Lancaster General Health Research Institute at 717-544-1777.

Other members of the LG Health staff who are conducting research and wish to have their studies described here are encouraged to contact the offices of JLGH at 717-544-8004.

SPORTS MEDICINE

Pediatric Concussion Outcomes - Treatment for Post-Concussive Headache: A Randomized, Placebo-Controlled, Double-Blinded Trial

Principal Investigator: Patrick Moreno, M.D.

According to the CDC,⁵ emergency departments treat more than 170,000 adolescents each year for activity-related traumatic brain injuries, including concussions. In most cases, physicians prescribe medication to alleviate symptoms and promote healing, but there is no consensus as to which medication is best.

This investigator-initiated study plans to determine if nortriptyline, in addition to standard post-concussion treatment, improves symptoms and helps patients return to sports and school faster. Children aged 13-18 who have a headache lasting four weeks or longer after a concussion are eligible to participate. These subjects will be randomized to

receive nortriptyline or a placebo in a blinded manner. Both groups will also receive standard-of-care treatment for their concussion. After four weeks, the blind will be broken and physicians, patients, and the patients' parents can decide what treatment option they want to pursue. Patients will be followed by the Research Institute for a total of six months. This study begins enrollment in February 2020.

WOMEN AND BABIES - NICU

Music Therapy for Stress Reduction in Premature Infants

Principal Investigator: Vivian Haughton

Preterm infants have a higher risk of developmental issues. While some have posited that music or sound therapy could overstimulate preterm infants, there is no evidence to prove this. In fact, recent studies have shown that music and certain sounds, such as heartbeats, can help improve development and lower the risk of brain injury.

This study will measure the effect of music therapy on oral feeding behaviors.

Infants will be randomized to one of two groups. Infants in the music therapy group will have an MP3 player placed in their room for three hours, twice a day, for 14 days in a row. The prerecorded sounds include heartbeat sounds, breath sounds, and a simple lullaby. Infants in the control group will not listen to the sounds or music. Researchers will look at weight gain, the number of days in the NICU, and other health issues common in preterm infants.

The study is overseen by Franklin & Marshall College and begins enrollment in the Spring of 2020.

HEART FAILURE**METEORIC-HF – Multicenter Exercise Tolerance Evaluation of Omecamtiv Mecarbil Related to Increased Contractility in Heart Failure****Principal Investigator: Tarek Nossuli, M.D.**

Many people with heart failure with reduced ejection fraction (HFrEF) experience symptoms such as dyspnea and fatigue, which limits activity. OM (omecamtiv mecarbil) is an investigational drug designed to improve the heart's pumping capability by activating cardiac myosin.

This double-blind, randomized, placebo-controlled, multicenter study aims to assess the effect of OM on patients' exercise capacity.

Patients who meet the study criteria perform a cardiopulmonary exercise test (CpET) at the start of the study, then are randomized to receive either OM or placebo twice a day for 20 weeks. The CpET is repeated at 20 weeks to evaluate changes in exercise capacity, peak oxygen uptake, and ventilatory efficiency. Investigators also record changes in the patients' daily activity.

ORTHOPEDICS**TAHFT – Evaluation of Tranexamic Acid Prior to Surgery in the Geriatric Hip Fracture Population for the Reduction of Post-Operative Blood Transfusion****Principal Investigator: Gregory Tocks, D.O.**

Many geriatric patients with hip fractures have comorbidities, including chronic kidney disease, congestive heart failure, ischemic heart disease, stroke, etc. These patients may also be anemic prior to surgery, and are at increased risk for further blood loss as a result of the fracture and surgery. However, intraoperative or postoperative blood transfusions increase their risk of renal and cardiac complications.

Tranexamic acid (TXA) is an anti-fibrinolytic medication that has been proven to limit blood loss associated with elective total joint replacement. This study examines whether geriatric patients requiring emergent hip fracture repair would benefit similarly from routine administration of TXA prior to the procedure. The need for transfusion during and after surgery will be compared in patients receiving either TXA or a placebo.⁶

REFERENCES

1. Small RS, Madara H. Spotlight on clinical research: cardiology and neurology. *J Lanc Gen Hosp*. 2018; 13(4): 100-101.
2. Small RS, Madara H. Spotlight on clinical research: nephrology, cardiology, radiology, neurology. *J Lanc Gen Hosp*. 2019; 14(1): 4-5.
3. Small RS, Madara H. Spotlight on clinical research: family medicine, cardiology, cardiothoracic surgery. *J Lanc Gen Hosp*. 2019; 14(4): 124-125.
4. Small RS, Madara H. Spotlight on clinical research: cardiology, cardiothoracic surgery, and trauma. *J Lanc Gen Hosp*. 2019; 14(3): 88-89.
5. <https://www.cdc.gov/headsup/basics/index.html>
6. <https://clinicaltrials.gov/ct2/show/NCT03923959?term=hip+fracture&recrs=a&cond=tranexamic+acid&fund=3&draw=2&rank=4>

Heather Madara
Penn Medicine LG Health Research Institute
131 E. Frederick St.
Lancaster, PA 17602
717-544-1777
Heather.Madara@penntmedicine.upenn.edu

Roy S. Small, M.D.
The Heart Group of Lancaster General Health
217 Harrisburg Ave.
Lancaster, PA 17603
717-544-8300
Roy.Small@penntmedicine.upenn.edu