Trauma and Acute Care Surgery Research Program

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Northeast Georgia Health System

Trauma Research

Clinical Trials:

Partial REBOA Outcomes Multicenter ProspecTive (PROMPT) STUDY SUMMARY

WHAT?

STUDY DESIGN:
A multi-center prospective observational study of non-compressible torso hemorrhage (NCTH) patients being treated with the pREBOA-PRO™ catheter for partial or full occlusion as standard of care.

Key Study Questions
1. Does pREBOA-PRO™ enable clinicians to perform partial REBOA in the emergent treatment of bleeding trauma patients?
2. Does partial REBOA provide clinical benefits such as decreased distal ischemia, extended safe occlusion time, improved hemodynamics during transition to and from occlusion, and reduced blood product use?

Key Endpoints
1. Time of occlusion
2. Ischemic markers
3. Tolerance to reperfusion
4. Blood product use

In patients receiving complete REBOA versus partial REBOA

WHY?

The DoD is funding a clinical study on partial REBOA using pREBOA-PRO™ to assess its impact on treating patients with NCTH, one of the leading causes of preventable mortality.

INVESTIGATORS:

Total Study Goal: 340 Subjects

Site Investigator
William Vassy, MD FACS
Director of Trauma and Acute Care Surgery | Trauma Medical Director

Principal Investigator
David Baer, PhD
CSO for Prytime Medical

TAP
TRAUMA AND PCC STUDY

PI: Dr. Timothy Stevens

Kcentra® (or 4-factor prothrombin complex concentrate) is a Food and Drug Administration (FDA) approved product that contains clotting factors. It is currently used to reverse the effects of medications given to "thin" the blood in patients, when such patients experience bleeding and/or require surgery.

There is evidence that Kcentra® may be beneficial (reduce the chance of dying) in injured patients who are not on blood-thinning medication. The TAP trial is a research trial to see whether Kcentra reduces the chances of injured people dying from their injuries.

WHO Patients who have been injured, and who are deemed to require a blood transfusion. We know that such patients are at high risk of dying.

WHERE The study will take place right here in our community, in patients cared for in our Emergency Department.

The TAP trial is a research trial to see whether Kcentra reduces the chances of people dying from their injuries because of blood loss.

HOW The treatment (Kcentra® or placebo) will be given as an IV (into a vein) infusion, which lasts about 10-15 minutes. The treatment will be given in addition to all usual care.

WHAT happens afterwards? There are no other research treatments once the infusion has been completed. We will record patient information and carefully monitor them for any complications.

TAP is one of the largest trauma trials ever conducted. It will involve up to 8,000 patients, across 140 hospitals (around 100 of them in the United States, the remainder in a small number of other countries).

Published Studies

Utility of an Emergency Department Observation Unit in Providing Care for Patients With Blunt Thoracic Trauma
Shehzad Muhamed [1], Matthew Vassy [2], Jason Konzelmann [1], Jesse Gibson [2], Leigh Pack [2]

Developing a Trauma Intermediate Care Unit
Krause, Morgan A. MSN-Ed, RN, PCCN; Mantooth, Jessica L. BSN, RN, CEN, TCRN; Gibson, Jesse E. MBA, BSN, RN, TCRN

Improving the Safety of Laparoscopic Cholecystectomy with Indocyanine Green Dye Using Critical View of Safety Plus
Michael P. Stolz, MD, Edward N. Forhall, MD, [...], and Molly M. McNamee, MD, +2 View all authors and affiliations

Navigating Trauma Patients and Families Through Unfamiliar Territory
Lee, Donna B. MSN, RN, CEN, TCRN

Adult golf cart injuries: A rising hazard off the course
Kyle Gibson, Timothy J. Stevens & Morgan A. Krause

Changing the Playing Field: A Prehospital Blood Product Pilot Project in Rural North Georgia
Nathan Creel, MD, Jesse Gibson, MBA, BSN, RN, Kyle Gibson, MSN, APRN, AGACNP-BC, Lissa Shirley, MSA, MT(ASCP)SBB, and Charles Richart, MD

Incarcerated Amyand Hernia Associated With Acute Appendicitis and Incidental Finding of Serrated Adenoma
Molly M. McNamee, MD, Michael P. Stolz, MD, [...], and Cecil Brown, MD, +1 View all authors and affiliations

Postintensive Care Syndrome: Feasibly Bridging Care at a Tertiary Trauma Center
Stevens, Timothy J. MD; Lee, Donna B. MSN, RN, CEN, TCRN

Evaluating the Effect of a Dosing and Titration Protocol on Dexmedetomidine-Induced Hypotension in Trauma Patients
Kurtz, Peyton M. PharmD; VanLandingham, Jason PharmD, BCPS; Cormican, Michael MD; Gibson, Kyle MSN, APRN, AGACNP-BC; Roebuck, Leslie PharmD

Formation of Biologic Plug and Patch Mesh for Use in Perforated Femoral Hernia
Michael P. Stolz, MD, James G. Chambers, MD, FACS, and Kamran Mahalati, MD, FACS View all authors and affiliations

Collaborative Approach to Organ Donation in a Level II Trauma Center
Jesse E. Gibson, MBA, BSN, RN, TCRN; Teisha Campbell, BS; Kyle Gibson, MSN, APRN, AGACNP-BC, TCRN; Kim Kottemann, MBA; Morgan A. Krause, MSN-Ed, RN, PCCN; Leigh Pack, BSN, RN

Streamlining care in two neurosurgical practices in a rural trauma center
Gibson, Kyle MSN, APRN, AGACNP-BC, TCRN; Whitson, Daniel MD; Filson, John D. MS, PA-C; Grunch, Betsy MD, FAANS, FACS; Pack, Leigh BSN, RN

Endoscopic Sleeve Gastroplasty Leading to Gastric Ischemia and Perforation
Michael P. Stolz, Brian H. Gibson, and William M. Vassy View all authors and affiliations

Traffic Injury Prevention

Journal of TRAUMA NURSING
OFFICIAL PUBLICATION OF THE SOCIETY OF TRAUMA NURSES

JAAPA AAPA

The American Surgeon™

AACN Advanced Critical Care

Cureus

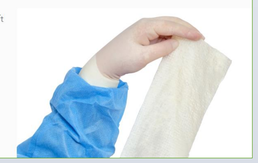
Acute Care Surgery Research

Current Multicenter Registry being conducted at NGMC Gainesville:
Registry of Myriad Utilization in Soft Tissue Reconstruction Procedures
PI: Dr. Matthew Vassy
Sub-PI: Dr. Michael Cormican
This registry involves patients undergoing plastic and reconstructive surgery procedures that involve the use of Matrix or Morcells.

Overview

Myriad Matrix™ is an engineered extracellular matrix (ECM) for soft tissue repair, reinforcement and complex wounds. Myriad Matrix™ has been specifically designed to help maximize tissue repair while providing versatility and adaptability across a wide range of surgical applications.

Myriad Matrix™ is designed to be easily customizable for a wide range of anatomical sites and surgical needs and can be used in both implantation and dermal repair.



Overview

Myriad Morcells™ is a morcellized (powdered) format of Myriad Matrix™ for soft tissue repair and complex wounds.

Myriad Morcells™ delivers a bolus of biologically important extracellular matrix (ECM) proteins that help kick start healing.

- The morcellized format of Myriad Morcells™ increases the AROA ECM™ surface area to maximize delivery
- Myriad Morcells™ easily conforms to optimize contact with irregular wound beds
- Myriad Morcells™ can also be conveniently hydrated in the tray

Clinical Trial Coming to NGMC Gainesville, Surgical Trauma Intensive Care Unit, Fall 2023:
Randomized Study of the pdSTIM System in Failure to Wean Mechanically Ventilated Patients (ReInvigorate Study)
PI: Dr. Bradley Kuhn
Sub-PI: Dr. Michael Cormican

What is the pdSTIM™ System?

The pdSTIM System™ is intended to provide temporary stimulation to facilitate weaning from mechanical ventilation in patients who have been on mechanical ventilation for 96 hours or more and who are at risk of having difficulty in weaning.

pdSTIM System

Therapy Set-up and Implementation

Place → Configure → Monitor

pdSTIM Leads are designed to enable minimally invasive placement at a patient's bedside in an ICU setting. The leads, which are placed trancutaneously in the neck region via ultrasound guidance, represent the world's smallest multielectrode lead (3 Fr) and fit through a needle enabling "through the needle" insertion. The pdSTIM Leads do not require placement via the vasculature nor near/within any organs. Since lead placement is not in the vasculature nor near/within any organs, there is a reduced risk of placement related complications and infections. The placement location also prevents interference with other lines or leads a patient may have.

Once the leads are placed and attached to the console, phrenic nerve stimulation is coordinated via the proprietary RespiSync™ algorithm and direct measurement of Work of Breathing (WOB) to produce physiologic diaphragmatic movement. The pdSTIM System is agnostic to the type or mode of ventilator.