UHealth Trauma Surgeons to Host Community Forums for Input on Blood Clotting Drug Study

Surgeons at the University of Miami Miller School of Medicine are seeking community feedback on a planned international study to investigate a blood clotting agent as a treatment for trauma patients who are bleeding to death.

Jonathan P. Meizoso, M.D., M.S.P.H.

“Bleeding out is the most common cause of preventable death after a traumatic injury,” said Jonathan P. Meizoso, M.D., M.S.P.H., assistant professor of surgery at the Miller School and a member of the surgical team at the University of Miami/Jackson Memorial Hospital’s Ryder Trauma Center. “We want to see if giving a blood clotting drug soon after arrival in the trauma center can save lives.”

Two virtual community forums, hosted on Zoom, are planned to discuss the Trauma And Prothrombin Complex Concentrate (TAP) Trial. The first will be April 13 at noon and the second April 24 at 6 p.m. Attendees will have a chance to ask questions and learn about trauma research from Dr. Meizoso, the site principal investigator for the TAP trial at the Miller School.
TAP Trial Will Evaluate Kcentra’s Effectiveness

The TAP Trial will evaluate the effectiveness of Kcentra®, in addition to standard care, in injured patients predicted to require a large volume blood transfusion. Kcentra® (or 4-factor prothrombin complex concentrate) is a U.S. Food and Drug Administration (FDA)-approved drug currently used to reverse the effects of medications given to “thin” the blood for patients who experience bleeding and/or require surgery.

“There is evidence that Kcentra® may reduce the chance of dying in injured patients who are not on blood-thinning medications,” said Dr. Meizoso. “Finding a way to improve patient survival rates is our highest priority here at Ryder Trauma Center.”

Patients in the study will have suffered a serious and potentially life-threatening injury causing significant blood loss and requiring immediate lifesaving interventions. These types of injuries occur unexpectedly, and it will not be possible for most people to sign up to participate ahead of time. Most patients will be unconscious, unable to speak or hear and too sick to consent to immediate treatment or participation in the study.

If the community feedback is positive and an independent review board approves the study locally, then researchers at the University of Miami and Jackson Memorial Hospital will participate in this trial, Dr. Meizoso said.

Community members who do not want to participate can request an “opt-out” bracelet. If consent is not feasible, patients
who fit the criteria will be automatically enrolled without their individual consent if they are not wearing an opt-out bracelet.

The TAP trial will be conducted in about 120 leading trauma centers in several countries and will include approximately 8,000 patients, making it the second-largest trauma trial ever conducted. The trial will begin in 2023 and last until 2026, and is funded by CSL Behring, a global biotherapeutics leader that makes prothrombin complex concentrate.

“The results of this study have the potential to change the way trauma patients are treated,” said Dr. Meizoso. “If we can determine that Kcentra® is safe and effective for trauma patients, we can transform the standard of care for bleeding trauma patients and save thousands of lives.”

- For more information regarding the TAP study, please click this link.
- To complete an anonymous survey on your thoughts about this exception from informed consent study, please go to the Ryder EFIC TAP Trial survey.
- To join the forum April 13 at noon, please use this Zoom link.
- To join the forum April 24 at 6 p.m., please use this Zoom link.