

OHSU Study To Improve Survival From Traumatic Injuries Begins

by Bend Weekly News Sources

Study is part of a national consortium to find the best methods for resuscitation outcomes at the site of injury. A study to determine whether a different type of resuscitation fluid than normal saline can improve survival rates in severely injured people will begin in the Portland metropolitan area this month. The study is the first as part of OHSU's partnership in the National Institutes of Health-funded Resuscitation Outcomes Consortium (ROC). The study was delayed so all hospitals in the consortium which could potentially receive subjects enrolled in the study could further standardize monitoring procedures. The Food and Drug Administration (FDA) asked that all hospitals have someone familiar with the study on staff and that sodium levels of enrolled subjects be checked regularly after admission. The current standard of care for treating people with traumatic injuries in the field is to intravenously administer saline (water with the same salt content as blood). This study will determine whether hypertonic saline (water containing more salt than blood) or hypertonic saline with dextran (an added sugar molecule) improves survival or brain function recovery. It is believed that hypertonic saline will allow blood flow to be restored with a smaller amount of fluid than regular saline, thereby reducing overexpansion of blood vessels which might worsen bleeding or swelling and by reducing inflammation following injury. The individuals eligible for this study will be severely injured, and therefore unable to provide informed consent. Because of this, the study will be conducted under FDA regulations that allow research of emergency treatments in certain life-threatening situations without the patient's pretreatment consent. The study was reviewed and approved by an independent panel of scientists chosen by the NIH, but not participating in the study design. The FDA approved the study and will continue to monitor the study for safety purposes in conjunction with local Institutional Review Boards (IRBs). "We undertake this study after intense local and national review," said Jerris Hedges, M.D., principal investigator, Greater Portland ROC site, professor of emergency medicine and vice dean in the OHSU School of Medicine. "The results of the study will likely guide the future choice of resuscitation fluid to be used by paramedics across all of North America. The potential benefit to citizens of the greater Portland area and beyond is great." To be eligible for the study, subjects must have severe injuries with either low blood pressure or an altered mental state due to head injury. OHSU expects most eligible subjects to be injured as a result of motor vehicle crashes. Women who are obviously pregnant, children 14 and under, and individuals under law enforcement arrest at the time of the incident will not be enrolled. Any community member who does not want to be included in this hypertonic saline study, or in future ROC studies that are carried out without individual advanced informed consent, can obtain a bracelet that opts them out of all such studies. The bracelet resembles a medical alert bracelet, and paramedics in the four participating counties are trained to look for them and exclude any person wearing this bracelet from the study. To obtain a bracelet, email roc@ohsu.edu and provide your full name and mailing address. More information about the Resuscitation Outcomes Consortium and the hypertonic saline study can be found at www.ohsu.edu/emergency/roc

OHSU Study To Improve Survival From Traumatic Injuries Begins by Bend Weekly News Sources