

Resuscitation Outcomes Consortium (ROC) Hypertonic Saline Trials

Study Description

The ROC Hypertonic Saline Trials were two multicenter trials of hypertonic resuscitation in two populations of trauma patients conducted simultaneously using the same intervention and infrastructure. The purpose of Study 1 was to determine the impact of hypertonic resuscitation on survival for blunt or penetrating trauma patients in hypovolemic shock. The purpose of Study 2 was to determine the impact of hypertonic resuscitation on long term (6 month) neurologic outcome for blunt trauma patients with severe traumatic brain injury. Both studies were three arm, randomized, blinded intervention trials comparing hypertonic saline/ dextran (7.5% saline/6% dextran 70, HSD), hypertonic saline alone (7.5% saline, HS), and normal saline (NS) as the initial resuscitation fluid administered to these patients in the prehospital setting.

Enrollment for both the shock and TBI cohorts was suspended on August 25, 2008. Enrollment for the shock cohort never resumed and the stopping of the trial in this cohort was announced by NHLBI on March 26, 2009. Enrollment resumed in the TBI cohort in November 2008. Enrollment in the TBI cohort was stopped in May 2009.

Major Study Publications

Brasel KJ, Bulger E, Cook AJ, Morrison LJ, Newgard CD, Tisherman SA, Kerby JD, Coimbra R, Hata JS, Hoyt DB; Resuscitation Outcomes Consortium Investigators. [Hypertonic resuscitation: design and implementation of a prehospital intervention trial](#). J Am Coll Surg. 2008 Feb;206(2):220-32. Epub 2007 Oct 18. PubMed PMID: 18222373.

Bulger EM, May S, Brasel KJ, Schreiber M, Kerby JD, Tisherman SA, Newgard C, Slutsky A, Coimbra R, Emerson S, Minei JP, Bardarson B, Kudenchuk P, Baker A, Christenson J, Idris A, Davis D, Fabian TC, Aufderheide TP, Callaway C, Williams C, Banek J, Vaillancourt C, van Heest R, Sopko G, Hata JS, Hoyt DB; ROC Investigators. [Out-of-hospital hypertonic resuscitation following severe traumatic brain injury: a randomized controlled trial](#). JAMA. 2010 Oct 6;304(13):1455-64. PubMed PMID: 20924011; PubMed Central PMCID: PMC3015143.

Bulger EM, May S, Kerby JD, Emerson S, Stiell IG, Schreiber MA, Brasel KJ, Tisherman SA, Coimbra R, Rizoli S, Minei JP, Hata JS, Sopko G, Evans DC, Hoyt DB; ROC investigators. [Out-of-hospital hypertonic resuscitation after traumatic hypovolemic shock: a randomized, placebo controlled trial](#). Ann Surg. 2011 Mar;253(3):431-41. PubMed PMID: 21178763; PubMed Central PMCID: PMC3232054.

List of Files Provided

pdf

Name	Filename(s)	Notes
Protocol	hs_protocol.pdf	
Protocol Appendices	hs_protocol_appendices.pdf	
Manual of Operations	hs_moo.pdf	
Data forms prior to August 2008 suspension of enrollment	hs_forms.pdf	The forms went through several revisions during the study. Important changes to data items are noted in the data dictionary.
Data forms for enrollment of TBI cohort only	hs_forms_tbi_only.pdf	After the shock trial was stopped, some data items related only to the shock cohort were removed from the forms.
News Release for shock cohort	hs_shock_stopping_news_release.pdf	NIH news release about the stopping of the shock trial.
News Release for TBI cohort	hs_tbi_stopping_news_release.pdf	NIH news release about the stopping of the TBI trial.
Data Dictionary	hs_data_dictionary.pdf	Includes variable names and codes as well as counts of records for each dataset.

SAS datasets

Dataset name	Records	Description
cases	2,220	This is the main dataset and includes one record per patient. The variable "hsid" is unique for each patient.
ae	381	Adverse events. This dataset has one record per adverse event. Patients may have multiple records. Records can be linked to the "cases" dataset by the variable "hsid".
cardventof	48,082	Includes data collected while patients were in the ICU. Patients with an ICU stay have 29 records in this table for days 0 (episode day) through 28. Each patient has 29 records regardless of how many days they spent in the ICU. There are 4 patients with an ICU stay who do not have any records in this dataset. The combination of "hsid" and "day" uniquely identify records in the dataset.
elec	11,908	Measurements of electrolytes. Patients may have multiple records in this dataset. See data dictionary for details about the source of the measurements. Records can be linked to the "cases" dataset by the variable "hsid".
hospcomp	314	Dataset includes one record per patient-complication (i.e. patients may have more than one record here). Patients without complications recorded are not included in the dataset. Records can be linked to the "cases" dataset by the variable "hsid".
hospinfect	1,018	Dataset includes one record per patient-infection (i.e. patients may have more than one record here). Patients without infections recorded are not included in the dataset. Records can be linked to the "cases" dataset by the variable "hsid".
hospproc	2,194	Dataset includes one record per patient-procedure (i.e. patients may have more than one record here). Patients without procedures recorded are not included in the dataset. Records can be linked to the "cases" dataset by the variable "hsid".
ms	2,133	This dataset includes the analysis populations for the shock and TBI primary manuscripts. Use "ms_shock eq 1" (or ms_tbi eq 0) to get the shock population and ms_tbi eq 1 (or ms_shock eq 0) to get the TBI population. Note that there is no overlap – shock/TBI patients were analyzed in the shock paper. One patient, a pregnant woman from the shock cohort analysis population, is not in this dataset.
tbigosedrsimp	1,282	This dataset includes actual and imputed 6-month GOSE and DRS scores for the TBI population. Records can be linked to the "cases" dataset by the variable "hsid".

Dataset name	Records	Description
tbiout	2,325	This dataset includes a record for each TBI outcome interview. TBI outcome interviews were taken at discharge, one month post discharge, and 6 months after episode. Records can be linked to the “cases” dataset by the variable “hsid”.
trtih	794	Includes treatments that required sodium monitoring. There are multiple records for patients with multiple treatments that required sodium monitoring. Patients without any treatments that required sodium monitoring are not include in the dataset. Records can be linked to the “cases” dataset by the variable “hsid”.

Software

Datasets were generated using SAS v9.3.