

***The OPALS
Prehospital Research
Group***



ONTARIO PREHOSPITAL ADVANCED LIFE SUPPORT STUDY

The Resuscitation Outcomes Consortium Studies:



Trauma Study

Hypertonic Resuscitation following Traumatic Injury



Purpose of the Study

- To determine if Hypertonic Saline with and without Dextran:
 - Improves overall survival
 - Improves outcome in victims of severe brain injury
- ...compared to Normal Saline.

HS Trial: Intervention

Three arm, randomized, blinded intervention trials comparing:

- Hypertonic saline / Dextran (7.5% saline / 6% Dextran 70) – HSD
- Hypertonic saline (7.5% saline) – HS
- Normal saline (0.9% saline) – NS

... as the initial resuscitation fluid administered to these patients in the prehospital setting (250cc)

Hypertonic Saline (HS) Trial

Two populations of trauma patients:

- 1.** Blunt or penetrating trauma patients in hypovolemic shock
- 2.** Blunt trauma patients with severe traumatic brain injury

Sample size

- Hypovolemic shock cohort will include approximately 3700 patients over 3.5 years
- Traumatic brain injury study will include approximately 2100 patients over 1.5 years

Inclusion Criteria

- Age ≥ 15 yrs (≥ 50 kg if age unknown)
- **Hypovolemic Shock**
 - Blunt or penetrating Trauma with:
 - SBP ≤ 70 mmHg OR
 - SBP 71-90 mmHg AND HR ≥ 108 bpm

AND / OR

- **Traumatic Brain Injury**
 - Blunt Trauma with
 - Prehospital GCS ≤ 8

Exclusion Criteria (Both Cohorts)

- **Known or suspected pregnancy**
- **Age <15**
- **Ongoing CPR**
- **Administration of > 2 litres of IV fluids**
- **Severe hypothermia (suspected T <28C)**

Exclusion Criteria (Both Cohorts)

- Drowning or hanging
- Burns > 20%
- Isolated penetrating injury to the head
- Inability to obtain intravenous access
- Time of call received at dispatch to study intervention > 4 hours ***

How are we doing?

ROC Enrolment Report

- **As of Thursday Oct 26th:**
 - **Total of 140 patients**
 - **Seattle ROC - 61**
 - **Toronto ROC – 37**
 - **OPALS – 30**
 - **British Columbia – 9**
 - **Dallas - 3**

ROC Enrolment Report

ONLY 5660 to go!

OPALS Enrolment Report

- **Total of 30 patients**
 - **Windsor – 13**
 - **Cambridge – 6**
 - **London – 4**
 - **Ottawa – 4**
 - **Kingston – 3**
 - **+ 9 Toronto ROC Air Ambulance patients in our OPALS hospitals**

Lessons Learned

- **Pt enrolment:**
 - **Question: “Did pt qualify for HS?”**
 - **Answer: “Almost, his GCS was 7 but he maintained his pressure”**
- **Protocol:**
 - **2 separate studies. For TBI use only GCS not BP**

Lessons Learned

- **Exclusion Criteria:**
 - **Time of call received at dispatch to study intervention > 4 hours**

- **The intention was to use this as a marker for time of injury**

Case study

- **Elderly male had a fall last night, hit his head very hard on concrete floor. Patient went to bed. This morning staff is unable to wake pt so 911 is activated. GCS 5. Unequal pupils. Hypertensive.**
- **Does patient qualify for HS?**

Lessons Learned

- **Tracking of missed cases**
 - **Shown to be a very effective training tool for the medics. Feedback should be given very early after the call**
- **Tracking of Fluid**
 - **Very important to monitor everyday to make sure that a patient isn't enrolled without us knowing**

Recent Events

- **Oct 26: Temporary suspension of enrolment**
- **Nov 16: FDA Allows Resumption of the Hypertonic Trauma Study**

Resumption of HS

- ...the FDA has re-approved (HS trial) after investigators developed additional data collection and monitoring techniques for follow-up care of patients...
- This includes 24/7 communication with hospitals for patient follow up

Changes to HS protocol

- **Changes affecting EMS providers:**
 - **Info sheet for ER staff in all fluid kits**
 - **Contacting study line immediately from ER and leaving:**
 - 1. Hospital Name**
 - 2. Patient Name**
 - 3. Fluid bag # (52-000-0)**
 - 4. Call #**
 - 5. Cohort (TBI or Shock)**

Changes to HS protocol

- **Other changes**
 - **Monitoring of Serum Sodium**
 - **Reporting of SAEs and AEs related to hypernatremia**
 - **Study Patient Oversight During Hospitalization**

Next steps

- REB approvals for amendment
- Obtain FDA 1572 from all Site Sub-Investigators
- Devise plan for getting all the fluid back onto the rigs in timely fashion

OPALS

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RESUSCITATION
OUTCOMES
CONSORTIUM



