

ProTECT III

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Second Annual Investigators' Meeting
April 2011

ProTECT III Investigators' Meeting Agenda

Friday, April 29th

7:15 – 8:00 am	BREAKFAST	ALL
8:00 – 8:45	Enrollment Reviews	Wright / Howlett-Smith
8:45 – 9:05	CST and Transgressions Review	Howlett-Smith
9:05 – 9:25	Monitoring and AE's	DeYempert/Howlett-Smith/Mawocha
9:25 – 9:55	Patient Tracking	Brandt/Hermanson/Howlett-Smith Mendoza-Moore/Ottman
9:55 – 10:15	BREAK	
10:15 – 11:45	Outcomes Review	Wright / Howlett-Smith
11:45 – 12:00	Contracts and Payments	Stevenson/Wright
12:00 – 1:00 pm	LUNCH / Open Discussion	ALL

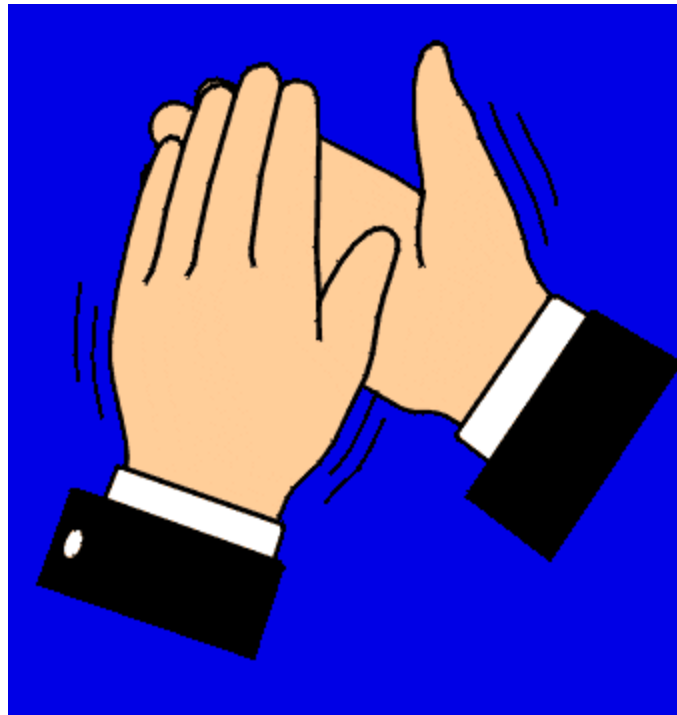
Enrollment Reviews – *Think Twice*

ProTECT III

Harriet Howlett-Smith

Age >18 years

- No subjects under the age of 18 have been enrolled!!!



Moderate to severe brain injury (iGCS 12-4)

- Make sure you get a good scene history (if the patient is talking at the scene, they don't qualify)
- Get a GCS off sedation shortly before enrollment

Able to initiate study drug infusion within 4 hours from time of injury

- #1 protocol violation (27)
- Do NOT randomize unless you have at least 20 minutes for pharmacy to mix drug
- Most are out of our control (pharmacy/OR)
- Once randomized you should start drug as soon as possible
- Do not delay starting drug infusion to consent family if they arrive
- If you don't have physical documentation (trip sheet) of the time of injury then be diligent about documenting conversations with EMS/Police/Family about time of injury.
- When monitoring occurs and physical documentation of time of injury differs from what was initially reported verbally, it is still considered a protocol violation

Blunt traumatic closed head injury

- TBI must be suspected in order to qualify for the study. For the purpose of this study, the definition of TBI is *an alteration in brain function, or other evidence of brain pathology, caused by an external force*. **It is important to recognize that factors other than TBI may be responsible for alterations in mental state at the time of the injury (e.g. pain, posttraumatic shock, medication, alcohol intoxication/abuse and/or recreational drug use)**. However, these confounders may be associated with the TBI and must be weighed in light of the history of injury.

thinking



Enroll or Not to Enroll?

Scenario 1

- 20 yo involved in MVC
- CT negative
- Head laceration
- ETOH level 249
- combative
- iGCS E₄V₁M₅ (intubated)

High ETOH/High GCS

- Is the altered GCS due to alcohol???
- Think twice before randomizing a GCS of 11-12 with ETOH on-board
- Repeat a GCS just prior to randomizing



Enroll or Not to Enroll?

Scenario 2

40 yo female fell down flight of stairs

2 minute Tonic/clonic seizure enroute to hospital

Ativan 2 mg IV given

Intubated for airway protection

iGCS E₁V₁M₄

Seizure/Post-Ictal

- Is altered GCS due to a post-ictal state?
- How long did the seizure last?
- Were benzo's given that could be affecting GCS?



Enroll or Not to Enroll?

- 98 yo male
- Unable to assess pupils b/c of cataracts
- On Coumadin
- Big Bleed on CT

Advanced Age

- Falls- What caused the fall?
- Concomitant medical conditions
- Is the treating team going to treat aggressively? (Even if they immediately take to the OR, will they continue to aggressively manage?)



Enroll or Not to Enroll?

Scenario 2:

- 69 year old male
- C/O not feeling well all day
- Went to bathroom and later found unconscious by family member
- Seizure enroute to hospital
- iGCS E₄V₁M₄
- Head hematoma
- Baseline Na⁺ 112

Abnormal Metabolic State

Is there a metabolic process that could be causing the altered GCS?

Example:

Hyponatremia symptoms include

- Confusion
- Lethargy
- Restlessness and irritability
- Decreased consciousness or coma

Lab Tests Online[®]
Your source. Not elsewhere. Please contact.

Sample Report

Different laboratories generate reports that can vary greatly in appearance and in the order and kind of information included. This is one example of what a lab report may look like. Names and places used have been made up for illustrative purposes only. Point your cursor at a highlighted area to learn about the different report elements.

University Medical Center, Dept. of Pathology 02/14/2008
123 University Way, City, ST 12345 10:13

Doe, Mr. John Q.

Patient ID No. 987654321 D.O.B. 01/01/1941 67Y/M
Ordering MD: Smith, Peter MD Physician Copy for Dr: Smith, Jane MD
PT Medications: multivitamins

Specimen(s) Collected: 2/10/08 14:30 Lab Acc'n No. 223456
Specimen: Serum Date Reported: 2/10/08 16:40
Comments: Specimen is non-fasting; st. hemolysis

Test Name	Patient's Results	Ref. Range	Units
SMO			
Na	HS, 1124	136-145	mEq/L
K	HS, 8	3.5-5.1	mEq/L
CO2	25	23-29	mEq/L
Cl	101	98-107	mEq/L
Glucose	H107	74-100	mg/dL
Ca	10.1	8.6-10.2	mg/dL
BUN	17	8-23	mg/dL
Creatinine	0.9	0.8-1.3	mg/dL

Key: L=Abnormal Low, H=Abnormal High, WNL=Within Normal Limits, *=critical value

Specimen(s) Collected: 2/10/08 14:30 Lab Acc'n No. 223457
Specimen: Blood Date Reported: 2/10/08 15:30

Test Name	Patient's Results	Ref. Range	Units
HGB	L7.0*	14.0-18.0	gm/dL
HCT	L21.1	42.0-52.0	%

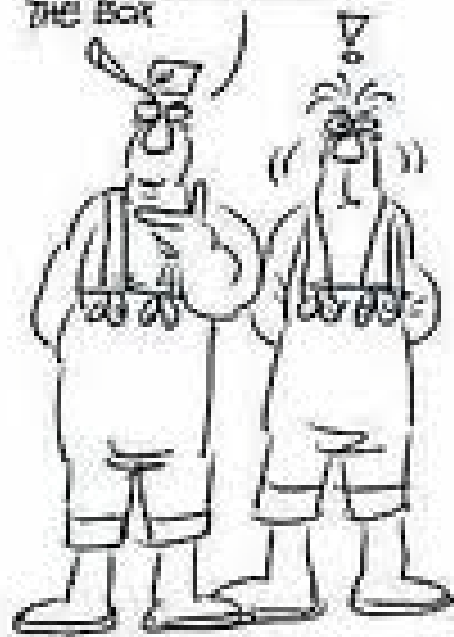
Comment: Hgb of 7.0 and Hct of 21.1 reported to Dr. J Smith at 15:15 on 2/10/08 by J. Doe

HGB A1c 4.8 4.3-6.1 %
Date Reported: 2/10/08 18:40

<http://www.labtestsonline.org/labtests/SampleReport.asp?testid=2772011 11/08/08 AM>

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IT'S TIME WE STARTED
PINKING OUTSIDE
THE BOX



WE HAVE A PROBLEM.
- WE'RE NOT IN A
BOX Y



search ID: jgm791

Logon IDs

- Please make sure you and your on-call staff regularly check logons for opt-out registry and WebDCU

Replacement Kits

- Reasons- extension tubing, leaking bag
- Replacement kit may not be from the same lot so VERY important to use dosing table contained within the kit for drug preparation from the replacement kit b/c the patient specific dosing table isn't updated when a replacement kit is generated
- Pharmacy manual updated

ProTECT Hotline

- 888-359-2221
- 24/7