Progesterone for Moderate-to-Severe Pediatric Traumatic Brain Injury - Pilot Study

Site:_____ **Subject ID:**_____

Name of Evaluating MD:_____ **Patient's MRN:**_____

***ACTION*:** Please complete this form for **every** patient < 18 years presenting to your ED with a GCS 3-12 after traumatic brain injury. *The front of this form is to be completed by the evaluating Physician, Fellow or Resident (with Supervising Attending Oversight). The back of this form is to be completed by RC.*
***PURPOSE*:** To evaluate feasibility issues for a future randomized trial of progesterone for children with moderate-to-severe TBI.
GOALS: Identify the number of eligible patients, patient demographics, and timing of patient and guardian arrival to the ED.

PHYSICIAN TO COMPLETE THE FOLLOWING QUESTIONS			
Inclusion criteria:			
• Is the patient < 18 years of age?	☐ Yes	☐ No	
• Does the patient have blunt head trauma?	☐ Yes	☐ No	
• Did the patient have a GCS of 3-12 on arrival at the study ED?	☐ Yes	☐ No	
If the answer is "No" to any inclusion criteria, then **STOP*			
Instructions: Provide the appropriate date & time for the following questions. NOTE: **For the arrival of legal guardian and time of patient's injury, if not documented, please provide your best estimate.**			
Date & estimated time of the **patient's injury?**	Date:____/____/_____ (MM/DD/YYYY) Time(24hr)____:____		
Date & time of **arrival** of patient's **legal guardian at the study hospital?**	Did the legal guardian ever arrive at the study hospital?: ☐Yes ☐ No *If yes, answer the following:* Date:____/____/_____(MM/DD/YYYY) Time(24hr)_____:_____ Was this time an estimate?: ☐ Yes ☐ No		
ED Questions:			
What was the patient's **GCS on arrival at the study ED**? • Date & time of GCS on arrival. • Was the patient pharmacologically sedated or paralyzed at the time of the arrival GCS evaluation? • Was the patient intubated at the time of the arrival GCS evaluation?	_____(3-12) Date:___/___/____Time____:____ (24 hr) ☐ Yes ☐ No ☐ Yes ☐ No		
What was the patient's **best GCS in the study ED?** • Date & time of the best GCS? • Was the patient pharmacologically sedated or paralyzed at the time of the best GCS evaluation? • Was the patient intubated at the time of the best GCS evaluation?	_____(3-15) Date:___/___/_____Time:____:____(24hr) ☐ Yes ☐ No ☐ Yes ☐ No		
Did the patient present in ED with a head injury resulting in penetration of the skull and brain?	☐ Yes	☐ No	☐ Unknown
Do you strongly suspect spinal cord injury with neurological deficits at the study ED?	☐ Yes	☐ No	☐ Unknown
Does the patient clearly have a non-survivable injury as determined by the treating team at the study ED?	☐ Yes	☐ No	☐ Unknown
Did the patient have cardiac arrest with CPR prior to presentation at the study ED?	☐ Yes	☐ No	☐ Unknown

Site:_____ **Subject ID:**_____

RESEARCH COORDINATOR TO COMPLETE THE FOLLOWING QUESTIONS			
Instructions: Please complete ALL sections listed below as well as any items above, under the "Physician variables", that are incomplete. Check with your site PI/Attending of record if you have difficulties answering any questions on this worksheet.			
Demographics:			
Patient's Date of Birth:	____/____/_____(MM/DD/YYYY)		
Gender	☐ Male	☐ Female	
Race (check all that apply)	☐ American Indian or Alaskan Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White or Caucasian ☐ Unknown		
Hispanic/Latino Ethnicity	☐ Yes ☐ No ☐ Unknown		
ED Questions:			
Date & time of patient's arrival at the study ED? (should be the earliest time documented)	Date:____/____/_____(MM/DD/YYYY) Time(24hr)____:____		
Was the patient transferred from another hospital?	☐ Yes	☐ No	
Mechanism of injury (check all that apply):	☐ MVC ☐ Pedestrian/bike injury ☐ Assault ☐ Fall ☐ Sports ☐ Other _____ ☐ Unknown		
Did the patient have a documented systolic blood pressure < 90mmHg for > 15 consecutive minutes in any ED?	☐ Yes ☐ No		
Did the patient have a documented systolic BP < 80mmHg for > 15 consecutive minutes in any ED?	☐ Yes ☐ No		
Did the patient have a documented systolic BP < 70mmHg for > 15 consecutive minutes in any ED?	☐ Yes ☐ No		
Was the patient's oxygen saturation documented to be <90% for > 15 consecutive minutes in any ED?	☐ Yes ☐ No		
Does the patient have a known history of active cancer (currently undergoing therapy)?	☐ Yes	☐ No	☐ Unknown
Does the patient have a known history of preexisting neurological disease which affects mental status (e.g. severe cerebral palsy)?	☐ Yes	☐ No	☐ Unknown
Does the patient have a known history of hypercoagualability or clotting disorder (such as protein C or protein S deficiency)?	☐ Yes	☐ No	☐ Unknown
Is patient known to be pregnant?	☐ Yes	☐ No	☐ Unknown
Is patient known to be allergic to eggs?	☐ Yes	☐ No	☐ Unknown
Was a blood alcohol level ordered at the study ED? If yes, what was the **first** result in the ED?	☐ Yes ☐ No _____(mg/dL or mmol/L)		
Date & time of **first** CT scan and upload radiology report. If radiology report is not available, please provide a brief interpretation by the attending MD in the space provided below:	Date:___/___/_____Time(24hr)___:___		
Did the patient die in the study ED? • If yes, provide date and time of death.	☐ Yes ☐ No Date:___/___/_____Time(24hr)___:___		

Site:_____ **Subject ID:**_____

RESEARCH COORDINATOR TO COMPLETE THE FOLLOWING QUESTIONS	
Inpatient Care Questions:	
Instructions: Please answer the following questions pertaining to patient's hospital stay. This includes both the ED and inpatient care unit.	
Did the patient receive intracranial pressure (ICP) monitoring at any time during the hospitalization? (See MOO for a listing of ICP monitors) • If yes, provide date and time of placement of Intracranial Pressure Monitor.	☐ Yes ☐ No Date:___/___/_____Time(24hr)____:_____
Did the patient receive an MRI of the head at any time during their hospitalization? • If yes, provide date and time of initial MRI.	☐ Yes ☐ No Date:___/___/_____Time(24hr)____:_____