Premie Cooling Trial
For Neonatal Encephalopathy

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September 19, 2015
Who’s Included?

- 33 o/7 weeks to 35 6/7 weeks gestation at birth
- ≥ 1500 grams
- < 6 hours postnatal age (must be randomized by 6 hours of life)

A. If blood gas available (cord, ABG, CBG, VBG) ≤ 60 min w/ pH < 7.0 or base deficit >16

B. If no blood gas or doesn’t meet criteria in “A” but has h/o acute perinatal event (asphyxia, dystocia, abruption, cord accident, uterine rupture) **AND**
   1. Apgars ≤5 at 10 minutes of life OR
   2. Assisted vent since birth and continued ≥10 min
Who’s Included? If meets criteria proceed to Neuro evaluation

- Seizures OR
- Signs of moderate to severe encephalopathy in $\geq 3$ of 6 categories on the Neuro evaluation. One of the Categories must be Altered Level of Consciousness
SARNAT=Encephalopathy Classification

1. Level of Consciousness
2. Spontaneous Activity
3. Posture
4. Tone
5. Primitive Reflexes
6. Autonomic System
Who’s Excluded?

- All blood gases $\leq 1$ hour of life with pH $>7.15$ and base deficit $< 10$
- Etiology of NE likely not due to Hypoxic Ischemia
- Major structural or chromosomal anomaly
- Full support will not be provided
- Core temp $< 34^\circ$C for $> 1$ hour
- Provision of clinical cooling
- Need for ECMO
Other Requirements

-HUS required before randomization or within 24 hours of randomization
-Certified Neuro exams can be done by the following MD’s: Bonifacio, Van Meurs, Chock, Hintz, Stevenson, Bhutani, Lee, Rhine, Akula, Palma